Ontario. [Commission and committees on the healing arts]

Study
[: No. 1] Private clinical laboratories in Ontario.

PRIVATE CLINICAL LABORATORIES IN ONTARIO

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CHEMICAL ENGINEERING
RESEARCH CONSULTANTS LIMITED

A STUDY FOR
THE COMMITTEE ON THE HEALING ARTS
1969

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FOREWORD

The Committee on the Healing Arts was established by the Province of Ontario, Order in Council 3038/66, dated July 14, 1966.

In June 1967, the Committee commissioned Chemical Engineering Research Consultants Limited of Toronto, Ontario, to undertake a study and survey of private clinical laboratories in Ontario. The following is a study prepared by this organization and submitted to the Committee in December 1967.

The statements and opinions contained in this study are those of the author, and publication does not necessarily mean that all the statements and opinions are endorsed by the Committee.

I. R. Dowie, Chairman
Horace Krever
M. C. Urquhart

PREFACE

In May 1966 a Commission was appointed by the Government of Ontario, the Committee on the Healing Arts, to "enquire into and report upon all matters relating to the education and regulation relevant to the practice of the healing arts". Specifically the Committee was asked to study ten aspects of the practice of the healing arts in Ontario, including item *(h)*:

> The present position and merit of the services, duties and responsibilities of those operating or engaged in providing services through independent biological or diagnostic laboratories.

This report documents the results of a survey of private clinical laboratories in Ontario carried out for the Committee by Chemical Engineering Research Consultants Limited (Toronto) during the period June to December 1967. D. Mackay, Ph.D., Professor of Chemical Engineering at the University of Toronto, directed the study and wrote the report, assisted by G. G. Smith, B.Sc.Phm., M.Sc.Phm., and R. D. Hossie, B.Sc.Phm., M.Sc.Phm.

Information and data were collected through several methods. First, the laboratories were asked to provide information on their organization, services and staff. A number of laboratories were inspected by the research team, and individuals and professional organizations associated with private laboratories were interviewed. In addition, we conducted a quality survey by submitting known samples to laboratories for analysis. On the basis of the accumulated data we were able to define the role and practices of private laboratories in Ontario and to select certain areas where change is desirable. We were able also to compare the quality of service offered by Ontario private laboratories with that of others outside the province.

To conclude our report we consider the problem of licensing and regulation, discuss alternative schemes, and make specific recommendations for the adoption of one of these by the Government of Ontario.

Throughout our investigations we were met with a generally high degree of cooperation, although there were some notable exceptions. Often there was strong initial resentment of non-medical persons asking questions about medical laboratories. In one extreme case, for example, the director warned us that we would "need an injunction to visit (his) laboratory". Most directors were very co-operative, however, and most professional organizations, especially the OMA, were very helpful.

D.M.

ACKNOWLEDGEMENTS

The assistance of the many members of the medical profession and technicians who contributed to this report is gratefully acknowledged. Any detailed list of acknowledgements to these persons would inevitably include errors of omission. They will recognize their own contribution.

The contribution of the following individuals deserves special mention: Mr. . West of Warner-Chilcott Laboratories Company Limited; the staff of the three eference laboratories, Toronto General Hospital, Toronto Western Hospital, nd the Public Health Laboratory, Toronto; and the author's colleagues in CERCL, articularly Dr. W. H. Rapson, Dr. W. H. Burgess, Dr. H. L. Williams, Dr. S. andler and Dr. W. F. Graydon.

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Chapter 1 Introduction

An essential part of the diagnosis and treatment of disease is the examination of material taken from the human body. This material, usually blood, urine or tissue, is most conveniently examined in a clinical laboratory which is organized to perform a variety of tests from a number of sources. Normally the laboratory is staffed by technicians under the direct supervision of a physician or pathologist who is responsible for the testing methods used and, in some cases, for the interpretation of results.

Recent Publicity

Recently there has been some public concern over reports that private laboratories do not exercise proper care and that test results are often "erroneous". In February 1967, Dr. D. J. Sencer, Director of the National Communicable Disease Center, Atlanta, Georgia, told a United States Senate subcommittee that

> Serious deficiencies have been demonstrated to exist in the Nation's clinical laboratories. Studies by the National Communicable Disease Center and others indicate that unsatisfactory performance is demonstrated by 10-40% of laboratories in bacteriological testing; by 30-50% in various simple clinical chemistry tests; by 12-18% in blood grouping and typing; by 20-30% in hemoglobin measurements; by 40-80% in differential characterization of blood cells; and by 20-30% in measurement of serum electrolytes. There also exists considerable variation in results from laboratory to laboratory. This information indicates that erroneous results are obtained in more than 25% of all tests analyzed by these studies. The results cited above were derived from performance evaluation programs and may represent the *best* which laboratories can do.[1]

Dr. Sencer went on to cite cases where death was caused by erroneous test results. This statement, which was widely publicized, has helped to strengthen the argument for interstate control of these laboratories. In 1968 only a few states required licensing, although many were considering the introduction of the necessary legislation.

According to at least one informant, the quality of testing in Ontario is probably worse than that in the United States.[2] It must be emphasized, however, that

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[1]Dr. David Sencer, Statement to Senate Committee on the Judiciary Subcommittee on Antitrust and Monopoly, February 7, 1967.

[2]J. C. MacLaurin, evidence before the Committee on the Healing Arts. Mr. MacLaurin is director of a group of private clinical laboratories based in Ottawa.

without statistics to back them up, any statements on the quality of testing are merely speculative; and the claim that a certain percentage of results is "erroneous" is invalid unless the term is defined. One objective of our study has been to appraise the situation in Ontario, to assess the quality of performance of Ontario laboratories (in comparison with laboratories elsewhere), and to estimate the extent of the danger to the public that results from inaccurate testing.

At present Ontario does not require that clinical laboratories be licensed; indeed, it is only in the past few years, with the substantial increase in private laboratory medicine, that there has been a need for legislation of this kind. There is in fact provision in the Public Health Act for regulations regarding licensing, and it appears that the Government of Ontario is planning to introduce such regulations in the not-too-distant future.

Tests Done by Private Clinical Laboratories

Of the 300 or so tests which can be done by medical laboratories, twenty common tests constitute about 90 per cent of the total work load. For the purposes of this report, it is convenient to divide the tests into a number of groups. The grouping we have used is the scheme adopted by the Ontario Medical Association in its Schedule of Fees.

1) *Biochemistry*
   Usually the estimation of the concentration of an element or compound in blood. For example, glucose, cholesterol or sodium.
2) *Blood Bank*
   Usually the determination of the blood group according to A, B, O and Rh types.
3) *Haematology*
   Usually the measurement of some property of the blood other than the blood group. For example, red or white cell counts, haemoglobin or clotting time.
4) *Microbiology*
5) *Cytology*
6) *Serology-Immunology*
7) *Pregnancy tests*
8) *Urinalysis*

Clinical testing is done by the following organizations in Ontario:

1) Private laboratories (the subject of this report)
2) Hospital laboratories
3) Public Health Department laboratories
4) Privately by a physician or a physician's employee.

There is no clear division between categories 1) and 4) since a technician employed by a physician may occasionally do work for other physicians. For the purpose of this report, a privately employed technician is not considered as constituting a private laboratory unless work is done on a regular basis for physicians other than the employer.

At the time of writing, there were 112 private clinical laboratories in Ontario. Because they vary considerably in ownership, in organization, and in services provided, we have found it convenient to classify them in three groups.

1) Private clinical laboratories offering the usual range of tests. This is the principal group and includes seventy-two laboratories.
2) Clinical laboratories which are part of "chains" of laboratories. There are four chains with a total of thirty-three laboratories.
3) Specialized laboratories offering only a narrow range of services. These seven laboratories do cytology, radio-isotope tests, pregnancy tests, allergy tests and renal analysis.

The laboratories in groups 1) and 2) are described in Chapters 2, 3, 4 and 5, and the specialized laboratories in Chapter 6.

All the clinical laboratories were contacted and data requested on the laboratory ownership, organization, staff, services, methods, equipment, and so on. Sixty-five of the laboratories were visited and information gained by both inspection and questionnaire. Twenty-seven of the laboratories provided information by questionnaire but were not visited, and twenty did not give any information at all. Prior to this survey very little data existed on the private laboratories in Ontario. No authoritative list existed and early estimates that there were only fifty or sixty laboratories were far from accurate. Now sufficient data have been obtained, it is hoped, to enable the Committee to assess the present situation and recommend changes, particularly through introducing regulations and controls.

The strategy in obtaining the necessary information for the Committee was as follows:

First, a survey was made of existing information on private laboratories in Ontario and elsewhere. Discussions were held with a number of individuals experienced in the subject, and a literature search was done of recent (since 1958) medical publications to obtain data on laboratory surveys.

Second, a list of laboratories was prepared.[3]

Next, a questionnaire was compiled, tested, and modified several times, with the object of obtaining the relevant information.

Fourth, laboratories were inspected using a standard procedure. Whenever possible the questionnaire was completed during the inspection; in other cases, it

[3]The laboratories are listed in Appendix I.

was sent and returned by mail. The inspection procedure was standardized by the inspectors initially visiting the laboratories in pairs or trios and comparing impressions later. Thus it was possible to make comparisons between laboratories visited by different inspectors.

Fifth, a quality survey was conducted by submitting known samples, specially prepared for this purpose, to the laboratories and determining the errors. A statistical analysis of the results was done to permit a comparison of Ontario private laboratories with others in Canada and abroad.

Sixth, many discussions were held with individuals interested in laboratory medicine and the diagnostic use of laboratory results. From these discussions we were able to draw some conclusions about the danger of inaccurate testing; present inadequacies of laboratories; and the need for, and preferred form of, licensing and regulation.

Professional Organizations

In the course of the survey a number of professional organizations were consulted whose members have a personal interest in private clinical laboratories. Most had submitted briefs to the Committee and many had appeared at the hearings. These organizations are listed below:

1) Ontario Medical Association
2) Canadian Medical Association
3) Canadian Society of Laboratory Technologists
4) Canadian Association of Pathologists
5) Ontario Association of Pathologists
6) Ontario Association of Medical Bacteriologists
7) Canadian Society of Clinical Chemists
8) College of Physicians and Surgeons of Ontario
9) Ontario Association of Medical Technologists.

Information was obtained also from professional organizations in the United States, including particularly the College of American Pathologists.

Chapter 2 Physical Resources and Practices

In this chapter we present data for private laboratories which are not members of any of the four large chains, and corresponding data for the chains of laboratories. The data are given in the form of percentages (for example, "50 per cent have ECG equipment"), rather than as exact numbers. The reason for this is that we were not able to obtain complete information from all laboratories. Some did not reply to the questionnaires at all, and some omitted a few answers; therefore we had to calculate percentages from the total replies we received.

While the data provide a reasonably accurate picture of private clinical laboratories in Ontario, they are not necessarily exact. In the first place, twenty laboratories on our list supplied no information. Second, there may be a few laboratories in the province which were not listed in our survey. And finally, the data were obtained during the period June to December 1967 and are now somewhat out of date. It is unlikely, however, that the true situation is significantly different from that described here and later in the report.

Location

Our principal sources of information in locating Ontario laboratories were OMSIP and PSI records. Warner-Chilcott also assisted us by giving us access to their files.[1]

There are seventy-two private clinical laboratories in Ontario. Seventy-five per cent are located in medical buildings; 8 per cent are in physicians' offices; and the remaining 17 per cent are in other buildings, including apartment buildings, private homes and rented commercial buildings.

Except for the more remote areas in the north, all areas of Ontario are reasonably serviced by clinical laboratories. Toronto is very well served, having twenty-two chain and thirty-one non-chain laboratories. Even if there is no independent laboratory in a particular region, the population may still have access to laboratory services, since hospital laboratories will do outpatient work and individual physicians can perform certain simple analyses themselves, often with the use of "kits" or prepackaged reagents.

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[1]The assistance of these organizations is gratefully acknowledged.

Size and Equipment

A laboratory usually consists of a laboratory area, a sampling room, a toilet, an office and a reception area. The average total area of a laboratory is 950 square feet. This may be divided, roughly, into 400 square feet of laboratory area, 300 square feet of office and reception area, and about 250 square feet for toilet and sampling rooms. Only 8 per cent of the laboratories in the survey did not take blood samples on the premises. Sixty-eight per cent had separate sampling (or bleeding) rooms; the remainder did not.

The laboratories contain the usual items of equipment for haematology and biochemistry. These include a microscope, a centrifuge, a spectrophotometer, the usual glassware and a refrigerator. The replacement value of the equipment in these laboratories averages about $8,500, roughly half being biochemistry equipment and half haematology equipment.

Three of the laboratories have automated equipment such as is found in large hospitals. The piece of equipment most often purchased is the autoanalyzer, which costs about $6,000. With this it is possible to do twenty to sixty analyses per hour at a much lower cost than manually, provided there are enough samples to be tested. Most laboratories, however, have insufficient work to justify the purchase of automated equipment. Ten per cent of the laboratories have x-ray equipment and 50 per cent have ECG equipment.

Although many laboratories have fairly old equipment, it is generally adequate for their purposes and in good repair. Some of the more prosperous laboratories have excellent modern equipment. The ultimate accuracy of the analysis, however, depends more on the way the equipment is used than on its age or cost.

An essential item in the laboratory is the procedure book, which describes exactly the method to be used for each analysis. Our inquiries revealed that the book was seldom referred to; and in some cases, it was nothing more than a rough assembly of notes. Some laboratories had several books. Thirty per cent of the laboratories had obtained books from hospitals or had photostated hospital procedure books. Twenty-five per cent had purchased books, and 50 per cent had compiled their own. Although no check was made of the correctness of the books, we suspect that many procedures are not up to date. Only 30 per cent of the laboratories subscribe to scientific literature such as journals in clinical pathology, pathology, clinical chemistry or medical technology. Most laboratories, therefore, have little contact with recent developments, although some undoubtedly rely on the director's access to such journals in a hospital.

In our inspection of the laboratories, one of the most revealing pieces of equipment was the refrigerator. Often it was crammed with vials, samples, bottles, sandwiches and milk. This untidiness is indicative of a poorly organized laboratory. The general cleanliness of the equipment and glassware often left a great deal to be desired, even with the housecleaning which probably preceded the inspection.

As a rule the technicians were very pleased to show their laboratory to the investigators, and were cooperative and interested in the Committee's work. In many cases the investigator had difficulty in terminating the inspection, because the director and technicians were eager to discuss clinical chemistry at some length.

Ownership

Thirty-three per cent of the laboratories in the survey have been incorporated. (Local requirements may necessitate a business licence, but this does not signify approval of a laboratory's standard of work.) The remaining 67 per cent were owned by an individual or by groups of individuals (usually physicians). This total is broken down as 45 per cent "privately owned" (principally by one owner) and 22 per cent "partnership". The form of ownership frequently is arranged to take maximum advantage of income tax deductions.

The owner distribution is as follows: 20 per cent are owned by one or more specialists (principally pathologists); 22 per cent by a physician with part pathologist ownership; 48 per cent by one or more physicians, possibly with a technician; and 10 per cent by chemists, technicians, non-profit making groups or municipalities.

If the analyses are to be paid by insurance, such as PSI or OMSIP, the principal owner of the laboratory must be a physician. Private laboratories are often criticized because a physician may purchase a share in a laboratory to enable it to obtain an insurance agreement, while sustaining no interest in or involvement with the laboratory — i.e., he acts only as a titular director. This criticism can be levelled equally at exclusively physician-owned laboratories in which the physician may leave the operation entirely to a technician. Only detailed inspection can disclose the extent of such practices.

A number of laboratories have ownership connections with others.[2] This has proved to be a very tangled web to unweave. In five cases the director or owner has interests in more than one laboratory. These small groups of laboratories differ from the chains in size only: no group includes more than three laboratories.

Compiling the information we obtained from each laboratory, we found that 50 per cent of them had been founded since 1963. Ten per cent were founded between 1960-1962, 25 per cent during the 1950's, and the remaining 15 per cent prior to 1950. During the last three years, new laboratories have been established at a rate of about eight per year. (This estimate does not include chains of laboratories.) In the absence of new restrictions, it would be reasonable to assume that this rate of growth will be maintained for some time. Also the amount of testing will tend to increase through the the expansion of existing laboratories. Changes in insurance payment arrangements or licensing regulations could, of course, considerably affect future growth.

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[2]For details, see Appendix I.

Services

All the laboratories in this group offered at least simple analyses in biochemistry, haematology and urinalysis. The distribution of analyses varies according to the laboratory's specialty. The following table shows the average and total amount of testing in each category for 1967:

	Average annual number of tests per laboratory	Total annual number of tests for all laboratories
Biochemistry	3,800	274,000
Blood bank	150	11,000
Haematology	10,400	750,000
Microbiology	300	22,000
Cytology	1,200	86,000
Serology-Immunology	430	31,000
Pregnancy tests	410	30,000
Urinalysis	2,200	160,000
Total	18,890	1,364,000

Biochemistry, urinalysis and haematology together constitute about 90 per cent of the work load. Most laboratories do pregnancy tests also; however, pregnancy testing usually is done by four commercial laboratories, who obtain much of their work through drug stores and without medical referral.

Comparatively little blood bank work is done. Blood grouping (A, B, O, Rh types) is one area where the patient's life may depend on the accuracy of the laboratory's analysis. In about one case per year in Ontario, death or serious illness is attributable to wrong grouping prior to transfusion. As far as we know, however, no transfusions are given in Ontario on the basis of private laboratory results alone (with the exception of the Kopp chain discussed later); a check is always made at the hospital as well.

About 40 per cent of the laboratories offer some microbiology services and 60 per cent serology. Thirty per cent offer cytology services; but because the demand is often insufficient to justify full-time employment of a cytology technician, one from a nearby hospital is usually employed part time in the evenings. Generally cytology testing tends to be done by specialized laboratories.

There is a strong argument for limiting laboratory services. Some laboratories, in an effort to meet their customers' special needs, attempt analyses which are beyond their abilities. This practice is inefficient, and the results are seldom satisfactory. Later in the report we make specific recommendations for limiting the range of analyses which this type of laboratory may perform. Special tests should be handled by specialized, fully equipped laboratories (such as commercial, hospital and public health laboratories), which are large enough and suitably staffed to meet the demand for service and to ensure accurate test results.

Almost all laboratories refer some work, often to public health or commercial laboratories. Samples are frequently sent also to commercial laboratories in California. Present insurance arrangements make no provision for paying a laboratory for such referrals, and many laboratories complain (justifiably) about this. It seems reasonable that a laboratory should receive some remuneration for referring a sample to another laboratory where the analysis can be done more accurately and at lower cost. To get around the problem, a number of laboratories send samples away and enter a claim against the insurers as if they had done the analyses themselves. This is less than honest; but we feel the practice is truly reprehensible only if a claim is made for an analysis which has been sent to a public health laboratory and done there free of charge.

The vast majority of tests are performed at the request of a physician. Pregnancy tests are the main exception, for which some laboratories accept test samples from drug stores. Analyses are very seldom requested by private individuals.[3]

Test results are sent on a special form to the physician who requested the analysis, and a copy is usually filed in the laboratory. The report normally is signed by the technician. The result may be telephoned in advance, if requested, or if the result is abnormal. Many pregnancy test results are sent by telephone only, and errors are sometimes made through mixing of samples and names. Fortunately a wrong pregnancy test result is often more confusing and inconvenient than dangerous.[4]

The test result seldom contains the method of analysis used (except in the case of glucose tests). It rarely reports the accuracy of the test expressed as a standard deviation or percentage error. About 85 per cent of the laboratories give normal values on the test note.

These normal values or ranges are taken from textbooks or procedure books, mainly because a private laboratory is unable (and probably unwilling) to calculate a normal range for its population of patients. Any questions which the physician may have on the test method, accuracy or normal range can be readily answered by a phone call.

Most laboratories in our survey (80 per cent) repeat analyses which fall outside the normal range, the remainder repeating only some. An abnormal result usually is brought to the notice of the physician by underlining or circling.

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[3]Occasionally a laboratory undertakes some veterinary work. One laboratory in our sample had done, over the period of a year, six electrocardiograms on horses, as well as the more usual analyses for haemoglobin, blood count and parasitology.

[4]There have been reports that abnormality may result in the child if a woman, not realizing that she is pregnant, continues to take birth control pills. These reports have not been fully proved, however, and it is believed that there is little or no danger to the public through errors made in pregnancy tests.

All the laboratories claim that their labelling and recording systems are such that samples never get mixed. Misidentification of samples probably does take place, but to what extent is unknown.

Fifty per cent of the laboratories provide a "home service" by which a sample can be taken from a patient by a visiting technician. This service is very valuable to patients unable to travel.

It is interesting to speculate on the degree of contact between physician and laboratory. The "average" laboratory deals with about twenty physicians: some with 200 or 300, and some with two or three. The laboratory usually informs physicians about changes in services personally, by letter, or by telephone. We attempted to estimate the amount of direct laboratory-physician contact by asking the laboratories how frequently physicians visited their premises. It appears that in medical buildings laboratory-physician contact is good, whereas in commercial laboratories many physicians rarely (and some never) visit the premises. Infrequent contact reflects poorly on the physician. It is clearly undesirable for him to send work to a laboratory which he knows little or nothing about. More discriminating choice of laboratory is to be encouraged.

Chains of Laboratories

There are four chains of laboratories in Ontario. As they differ from each other and from other laboratories in ownership and supervision, we will discuss them separately.

Toronto Medical Laboratories Limited

This chain consists of five laboratories, four in Toronto and one in Oakville. The sole owner and director is Dr. Dorothy C. H. Ley, M.D., B.Sc.(Med.), F.R.C.P. (C), F.A.C.P, part-time Director of Haematology at Toronto Western Hospital (a position Dr. Ley is resigning) and an Assistant Professor at the University of Toronto.

The principal laboratory is Western Medical Laboratory, which was founded in 1959. The others (North Toronto, Kingsway, Keele-Ingram and Oakville) were founded during the period 1962 to 1966. The four new laboratories perform limited services, referring more demanding work to the principal laboratory. All do the common haematological tests and urinalysis, and two do simple biochemical tests.

The four Toronto laboratories are located in medical buildings, the Oakville laboratory in a house. The principal laboratory is fairly large (1,200 square feet) but cramped in view of the amount of work done there; Oakville is spacious (925 square feet), and the other three are typical compact medical building laboratories of about 420 square feet each. A new more spacious location is planned for the Western laboratory in Etobicoke.

The principal laboratory does about 73,000 tests annually. No cytology or microbiology is done, and very little pregnancy testing or blood grouping. Biochemistry accounts for about 60 per cent of the work, haematology for 35 per cent, and the remainder is principally serology. Some radio-isotope testing is done. The other laboratories average about 9,000 tests each, 90 per cent of which are haematology and about 5 per cent each urinalysis and biochemistry. The total work load of the chain is thus about 110,000 tests annually.

The Oakville laboratory also cooperates with the local hospital in providing electrocardiograms to the extent of 109 per year.

All the laboratories were visited, and found to be above average in cleanliness, with equipment that was good and well maintained. The total equipment replacement value is about $50,000.

The technical staff totals twenty-four, six of whom are part-time summer employees. The director spends about twenty-five hours per week in the Western laboratory and five hours in each of the others. A chief technician is in charge of all laboratories, and each laboratory is visited daily by either the chief technician or the director. Nine technicians are R.T.'s (registered technicians) and another nine have qualifications from abroad (four B.Sc.'s from the Philippines) or hospital experience. The smaller laboratories are staffed by two technicians.

An active quality control system is maintained between the laboratories and the degree of supervision is adequate, the laboratories being well run and controlled. The author's observations and experience lead him to conclude that this represents the largest size of laboratory chain which can be supervised by one professional person.

Kopp Clinical Laboratories

This chain consists of eight laboratories and three specimen collection centres. The principal laboratory and office is in Ottawa, one is in Toronto, and the remainder are located on hospital premises in the Ottawa Valley (Almonte, Arnprior, Carleton Place, Kemptville, Perth and Shawville, P.Q.). The chain was incorporated in 1949 and now is owned by a group of fourteen physicians. The executive director is Mr. B. B. Czap, R.T., B.A. A number of consultants are retained.

The chain runs laboratories in six hospitals, owning the equipment and hiring and controlling staff, but not owning the premises. In addition to analyses for these hospitals, the chain takes referred work from fourteen other hospitals and twelve other institutions (homes and private hospitals), and from practising physicians in Ontario and Quebec.

A very comprehensive range of tests is done by all the laboratories: a total of 170,000 tests are done annually, 50 per cent of which are haematology, 36

per cent biochemistry, 8 per cent bacteriology, and the remainder principally blood bank. This chain is unique in providing blood bank services to hospitals.

The laboratories were all visited and found to be well organized, with adequate equipment. The principal problem facing the company is shortage of staff. Of the total technical staff of twenty-two, seven are full-time R.T.'s, two are part-time R.T's, and thirteen are non-registered technicians. This means that some laboratories do not have an R.T. in charge. The staff shortage has been met by providing an internal course for staff. The course is well organized and complete, but is not subject to inspection from outside agencies and leads to no formal qualification. This training program is more extensive than any offered by other private laboratories.

An internal quality control program is maintained by submitting known samples to the laboratories from the reference laboratory. The level of supervision by the director (Mr. Czap) is necessarily low, since the laboratories are spread over a wide area. More details concerning the operation of these laboratories have been submitted in a brief to the Committee and in their response to Questionnaire E of the Committee.

Doctors' Clinical Laboratory

This chain has five laboratories: three in Ottawa, one in Toronto, and one in Brantford. The chain was incorporated in 1960 and is now run by a Board of eleven directors, J. C. MacLaurin being the Managing Director. Six of the directors are physicians, and three consultants are retained. The company has thirty shareholders.

The principal laboratory on Hinton Avenue, Ottawa, receives work from the other Ottawa laboratories. The two laboratories outside the capital for the most part operate separately, and the Brantford laboratory is controlled from Toronto. The premises are of average size — i.e., 400 to 900 square feet. We did not visit the Brantford laboratory, as there are plans to close it. The other laboratories were found to be of average quality, having good, well-maintained equipment. The replacement value of equipment is about $40,000.

The chain offers a comprehensive range of services, the Ottawa laboratories doing about 23,000 tests annually and the Toronto laboratory about 11,000 tests annually. The distribution is 40 per cent haematology; 50 per cent biochemistry; and the remainder urinalysis, cytology, serology, microbiology and pregnancy tests. Some biochemistry is sent to Ottawa, and cytology is done only in Toronto.

The technical staff consists of eleven technicians, five of whom are R.T.'s, the remainder having a variety of qualifications. There is some staff training, and two "students" are employed. Medical supervisors (physicians who are on the Board of Directors) are assigned to each laboratory. However, direction is essentially in the hands of Mr. MacLaurin in Ottawa and an R.T. in Toronto.

The chain has a system of quality control in operation and is about average in laboratory and staff standards.

Pathologists' Services

This chain of sixteen laboratories in Toronto is supervised by a group of three pathologists, Dr. B. Balshin, Dr. L. Blevis and Dr. I. M. Cass. Drs. Balshin and Blevis hold appointments at the Doctors' Hospital, Toronto. The only laboratory which is owned by the group is Hillside Laboratory. The other laboratories are owned by various groups of physicians, most of whom occupy the medical building in which each laboratory is located. The staff are generally employed by and paid by the owners. The contribution of Pathologists' Services is the hiring, partial training, and supervision of staff; laboratory planning; the purchase of equipment and chemicals; responsibility for quality control and for methods of analysis used. All the laboratories use the same methods, the same chemicals, and the same equipment, and are subjected to the same quality control procedure. This means that staff can be moved freely to any laboratory as the need arises.

The financial arrangement is that a percentage of the analysis fee is given to Pathologists' Services in payment for supplies and for professional assistance from both the pathologists and the technicians who do the day-to-day maintenance, inspection and trouble-shooting.

The amount of supervision by the group is difficult to assess since it varies considerably, depending on the requirements of the particular laboratory. A smooth-running laboratory is left substantially alone, whereas a laboratory with problems may receive intensive supervision. An estimate of supervision can be made as follows. The three pathologists each spend about one-quarter of their time in the laboratories — i.e., a total of thirty to forty hours per week, or two hours per laboratory per week. In addition, three senior technicians who are employed at the Doctors' Hospital spend about one-third of their time in the laboratories. This amounts to about three hours per laboratory per week. At other times the laboratories usually are supervised by one or two technicians.

The laboratories vary considerably in size and amount of work. Most were visited and the overall standard seemed about average, with some laboratories having a fairly low standard of cleanliness. Some of the laboratories operate on an intermittent basis.

The total work load is about 242,000 tests per year. This is substantially larger than any other chain. The average per laboratory is about 15,000 tests per year (a typical work load for a medical building laboratory). Three laboratories (Parkdale, Professional Medical and North York Diagnostic) do over 40,000 per year, whereas two (Willowdale and Keele) operate only occasionally and do about 1,000 per year. Hillside was expected to start work early in 1968. The range of tests is comprehensive and most laboratories tackle a fairly wide range of analyses; some are referred to the larger central laboratories. Since the

organization has sufficient work to justify centralization, certain analyses will probably be handled only at the Hillside Laboratory. This will effect a considerable economy to the organization; but unless the fee payment structure is reviewed, the saving will not be realized by the customer.

The laboratory staff consists of thirty-one technicians, twenty-two of whom are R.T.'s. The percentage of R.T.'s is thus higher in this chain than in other chains or in laboratories at large. The equipment replacement value is about $4,000 per laboratory.

The pathologists are available for interpretation of test results; and they conduct a program of education for physician-clients, discussing the latest developments in laboratory medicine and the use of laboratory results. They also see all cytology samples.

Economics of Private Clinical Laboratories

The laboratories were asked to state the percentage of their work which was known to be covered by insurance. This often proved to be difficult to answer, but it is estimated that about 90 to 95 per cent of insurable laboratory work is covered by medical insurance.

The profitability of these laboratories is not easily assessed. One group of laboratories, the Kopp chain, provided a breakdown of their annual turnover, showing the profit to be about 6 per cent of the total turnover. There is very little doubt that the OMA Schedule of Fees gives quite a generous fee for the amount of work done. This is partly because the fee includes an allowance for interpretation by a pathologist and this interpretation does not normally take place. The Schedule of Fees for biochemistry and haematology states that: "This Schedule of Fees is to apply to the practice of Clinical Pathology by or under the direction of a qualified Clinical Pathologist." The Schedule is still applied in the absence of a pathologist.

Comparatively little analysis is done under the direct supervision of a clinical pathologist. In some cases laboratories commented that the fee which they received was too generous and they would welcome a reduction.

One unfortunate feature of the economics of private laboratories is that effective quality control tends to be expensive.[5] It is very easy to economize by reducing the amount of quality control; and the impression was frequently gained on visiting the laboratories that less scrupulous directors effected such economies.

The whole economic picture alters drastically when automation is introduced and still further if multi-screening tests are used. From talking to a number of

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[5]A small vial of quality control serum typically costs between $1.00 and $5.00. Such a vial is suitable for doing about five analyses.

laboratory directors we surmised that they fully expected the OMA Schedule of Fees would remain in operation despite the introduction of automated equipment. This will result in an enormous profit to the laboratory. It is to be hoped that some of the savings which are effected by automation will be passed on to the public by some alteration in the OMA Fee Schedule. Accordingly, it is found that:

> The OMA Fee Schedule requires immediate review, particularly with the object of passing on to the public savings arising from automation and reconsidering the applicability of the professional interpretative component of the fee in private laboratory analyses.

Advertising

We made inquiries to find out how laboratories advertised and solicited new business. The answers were as follows. Seventy per cent of the laboratories did not solicit new business at all, relying entirely on their existing customers and on personal contact with any new physician who moved into the region; some laboratories would approach a physician who had set up practice in their locality and supply him with a list of tests which they offer, along with blank requisition forms. The remaining 30 per cent spent some amount of money on advertising — for example, in the Yellow Pages under "Laboratories" — and some quite actively solicited new business from physicians. Most laboratories did not feel themselves bound by the same ethical considerations that restrict physicians in advertising.

A typical requisition form and fee list are given in Figures 1 and 2.

The accusation was made that some laboratories deliberately chose names to suggest some connection with a hospital. Instances were cited where patients mistakenly went to a private laboratory instead of the hospital, and considerable confusion ensued when the physician queried the analysis or the account.

Name of Patient .....

Address .....

Physician .....

Address ..... Phone .....

Date: ..... Previous examinations: Yes/No

Time: .....

☐ CHARGE PATIENT ☐ BILL DOCTOR ☐ PHONE REPORT

PLEASE CHECK TESTS REQUIRED BELOW

• BACTERIOLOGY •

☐ ANTISTREPTOLYSIN TITER
☐ LATEX FIXATION
☐ PAUL BUNNELL
☐ NASAL SMEAR FOR EOSINOPHILS

• BIOCHEMISTRY •

☐ AMYLASE
☐ BILIRUBIN — DIRECT
☐ BILIRUBIN — TOTAL
☐ BROMOSULFALEIN
☐ CALCIUM
☐ CAROTENE
☐ CEPHALIN FLOCCULATION
☐ CHLORIDES
☐ CHOLESTEROL
☐ CO_2 COMBINING POWER
☐ CREATININE
☐ GLUCOSE TOLERANCE TEST
☐ SERUM IRON
☐ IRON BINDING CAPACITY
☐ LACTIC DEHYDROGENASE
☐ PHOSPHATASE — ACID
☐ PHOSPHATASE — ALKALINE
☐ PHOSPHORUS
☐ POTASSIUM
☐ PROTEIN BOUND IODINE
☐ PROTEINS — TOTAL
☐ PROTEINS — ALBUMIN
☐ PROTEINS — GLOBULINS
☐ SERUM ELECTROPHORESIS
☐ SODIUM
☐ SUGAR
☐ THYMOL TURBIDITY
☐ TRANSAMINASE
☐ UREA NITROGEN
☐ URIC ACID
☐ SPINAL FLUID — CHLORIDE
☐ SPINAL FLUID — PROTEIN
☐ SPINAL FLUID — SUGAR
☐ 17-HYDROXYCORTICOIDS
☐ 17-KETOSTEROIDS
☐ SEROTONIN
☐ VMA

• URINALYSIS •

☐ COMPLETE (Chemical and Micro)
☐ CHEMICAL ONLY
☐ MICROSCOPIC ONLY
☐ BENCE-JONES PROTEIN
☐ CALCIUM
☐ MOSENTHAL TEST
☐ PORPHYRINS (QUALITATIVE)
☐ PORPHYRINS (QUANTITATIVE)
☐ PREGNANCY TEST (A-Z)
☐ QUANTITATIVE ALBUMIN
☐ QUANTITATIVE SUGAR
☐ QUANTITATIVE CHLORIDE
☐ UROBILINOGEN (QUALITATIVE)
☐ UROBILINOGEN (QUANTITATIVE)

• SEROLOGY •

☐ BLOOD GROUP
☐ V.D.R.L. (WASSERMAN)
☐ RH TYPE
☐ COOMB'S TEST (DIRECT)
☐ COOMB'S TEST (INDIRECT)

• RADIOACTIVE ISOTOPES •

☐ RADIOACTIVE IODINE UPTAKE
☐ SCHILLING TEST

• HAEMATOLOGY •

☐ BLEEDING TIME
☐ CLOT RETRACTION
☐ CLOTTING TIME
☐ COMPLETE BLOOD COUNT
☐ DIFFERENTIAL COUNT
☐ DIFFERENTIAL ON BUFFY COAT
☐ EOSINOPHIL COUNT
☐ FRAGILITY
☐ HAEMATOCRIT
☐ HAEMOGLOBIN
☐ L.E. CELLS
☐ MALARIA PARASITES
☐ PLATELET COUNT
☐ PROTHROMBIN TIME
☐ RED BLOOD COUNT
☐ RETICULOCYTE COUNT
☐ SEDIMENTATION RATE
☐ SICKLE CELLS
☐ SMEAR
☐ STIPPLED CELLS
☐ WHITE BLOOD COUNT

• MISCELLANEOUS •

☐ BONE MARROW BIOPSY AND DIFFERENTIAL COUNT
☐ FIBRINODEX SCREENING
☐ FIBRINOGEN
☐ FIBRINOLYSIS
☐ GASTRIC ANALYSIS (TUBELESS)
☐ PROTHROMBIN CONSUMPTION
☐ THROMBOPLASTIN GENERATION

• OTHERS •

Please Specify: .....

.....

.....

.....

FIGURE 1 REQUISITION FORM

HAEMATOLOGY

Bleeding Time	2.00
Blood Smear Interpretation	6.00
Blood Film, Special Stains	10.00
Bone Marrow Aspiration only	10.00
Aspiration and Interpretation	25.00
Interpretation	10.00
Chromosome Analysis, Karyotype	50.00
Clot Retraction	1.00
Clotting Time	2.00
Complete Blood Count	6.00
Differential	2.00
Differential and Report on Film	4.00
Eosinophil Count	2.00
Fibrinogen Estimation	6.00
Fibrinogen Screening (Fibrindex)	2.50
Fibrinolysis (Presumptive)	2.00
Fragility Test	6.00
Haematocrit	2.00
Haemoglobin	2.00
Haemolysins: Acid	3.00
Cold	3.00
L.E. Cells	5.00
Malaria or other Parasites	5.00
Nasal Smear for Eosinophils	2.00
Partial Thromboplastin Time	3.00
Platelet Count	4.00
Prothrombin Consumption	10.00
Prothrombin Time	2.00
Red Blood Cell Count	2.00
Reticulocyte Count	3.00
Sedimentation Rate	2.00
Sickle Cells	4.00
Smear Only	2.00
Stippled Cells	3.00
Thromboplastin Generation	25.00
White Blood Cell Count	2.00

BIOCHEMISTRY — Blood

Amylase	4.00
Bilirubin (direct)	3.00
Bilirubin (total)	3.00
Bromosulphalein	5.00
Calcium	4.00
Carotene	4.00
Cephalin Cholesterol Flocculation	3.00
Chlorides	3.00
Cholesterol — Total	4.00
Free and Ester	8.00
Congo Red Test	5.00
CO_2 Combining Power	5.00
Creatinine	3.00
Creatinine Clearance	5.00
Cryoglobulins	3.00
Electrolytes (Na, K, Co_2, Cl)	10.00
Electrophoresis (serum proteins)	10.00
Gastric Analysis (tubeless)	2.00
Glucose	3.00
Glucose Tolerance Test	10.00
Glucose-6-Phosphate Dehydrogenase (G-6-PD)	5.00
Hemoglobin Fractionation (electrophoretic)	15.00
Icteric Index	1.00
Iron (serum)	5.00
Iron-Binding Capacity	8.00
Isocitric Dehydrogenase (I.C.D.)	5.00
Lactic Dehydrogenase (L.D.H.)	5.00
Lipase	5.00
Lipids (total)	5.00
Lipids (phospholipids)	10.00
Lipids (non-esterified fatty acids)	12.00
Lipids (Triglycerides (neutral fats))	5.00
pH Blood	5.00
pCO_2 Blood	5.00
Phosphorus	5.00
Phosphatase (acid)	5.00
Phosphatase (alkaline)	5.00
Potassium	3.00
Proteins (albumin)	3.00
Proteins (electrophoresis)	12.00
(Total)	3.00
(A/G Ratio)	5.00
Proteins (globulins)	3.00
Protein Bound Iodine	6.00
Quinidine Level	5.00
Salicylates	5.00
Spinal Fluid (chlorides)	3.00
Spinal Fluid (protein)	3.00
Spinal Fluid (sugar)	3.00
Sodium	3.00
Thymol Turbidity	3.00
Transaminase (S.G.O.T.)	5.00
(S.G.P.T.)	5.00
Urea Nitrogen	3.00
Uric Acid	3.00
Vitamin A	10.00
Xylose Excretion Test	10.00

BIOCHEMISTRY — Urine

Calcium	5.00
Catechol Amines	25.00
Chlorides	3.00
Chorionic Gonadotrophin (quantitative)	25.00
Estrogens (total)	20.00
F.S.H.	30.00
Porphyrins (screening test)	2.00
Porphyrins (total)	8.00
Porphyrins (coproporphyrins)	5.00
Porphyrins (porphobilinogen)	5.00
Porphyrins (uroporphyrins)	5.00
Potassium	4.00
Pregnanediol	20.00
Pregnanetriol	25.00
Serotonin (see 5-H.I.A.A.)	
Sodium	4.00
Uric acid	4.00
Vanillylmandelic acid (V.M.A.)	25.00
5-Hydroxyindoleacetic acid (5-H.I.A.A.)	
Screening	2.00
Quantitative	20.00
17-Hyrdoxycorticosteroids	20.00
17-Ketosteroids	15.00

RADIOISOTOPE TESTS

Blood Volume	20.00
Erythrocyte Survival (Cr^{51})	50.00
Fat Absorption (I^{131})	25.00
with Plasma Levels	50.00
Iron Absorption (Fe^{59})	20.00
Iron Clearance	25.00
Iron Clearance and R.B.C. Uptake	100.00
Schilling Test	20.00
T3 (Sponge Resin Uptake)	8.00
T4 (Thyroxine)	10.00

THYROID FUNCTION TESTS

Butanol Extractable Iodine	10.00
Protein Bound Iodine	6.00
Radioactive Iodine Uptake	10.00
T3 Test	8.00
T4 Test	10.00
Thyroid Auto-Antibody Test	3.00

Chapter 3 Personnel

Classes of Personnel

In this chapter we discuss separately the work, qualifications and responsibilities of the various classes of personnel who staff private clinical laboratories.

Director

Since over 90 per cent of clinical laboratory work is covered by insurance (principally OMSIP and PSI), laboratories obviously find it desirable to meet the insurer's conditions regarding the qualifications of their director. Essentially he must be a licensed physician. PSI also requires that the laboratory be owned (at least 51 per cent) by a physician and that the director should be in "day-to-day" supervision. Neither OMSIP nor PSI inspects laboratories.

Ideally, all laboratory directors should be pathologists with specialized knowledge, as other physicians usually have had only superficial training in laboratory techniques and interpretation of results. The requirement that the director should be a licensed physician in no way guarantees that he has the ability to supervise a clinical laboratory, and some clinical laboratories are criticized for being under the direction of a physician who is a "titular" director.

Several physicians and pathologists who were interviewed in the study stated that they had been approached by private laboratories with a view to being appointed as consultants. It was made clear that the consulting activities would be minimal and that the remuneration would be in return for the prestige and possible respectability which their names would bring to the laboratory.

It is generally recognized that there is a shortage of pathologists and clinical chemists in Ontario. If every private laboratory had to have as its director a pathologist or clinical chemist who must spend, say, ten hours per week in the laboratory, then most private laboratories would close down.

There are two factors which tend to minimize professional involvement in private laboratories. One is the shortage of qualified people. The other is that the directorship probably brings little reward in terms of personal and professional advancement and satisfaction, although it may bring financial rewards. It is believed that most professionals value the research opportunities offered by hospitals and the contact there with other specialists. A life devoted entirely to one or more private laboratories is by comparison dull.

Present insurance regulations do not acknowledge clinical chemists as qualified laboratory directors. This, and the fact that the position offers them a mini-

mal degree of professional satisfaction, explains why there are relatively few clinical chemists attached to private laboratories (in 1967, only 5 per cent of the Canadian Society of Clinical Chemists in Ontario). While a pathologist may combine the satisfaction of a private practice or a hospital appointment with his private laboratory interests, a clinical chemist is more likely to devote himself entirely to a hospital where he can pursue research in addition to his laboratory duties. A private laboratory will be of small professional interest and almost certainly will offer no advantages for research. However, there is little doubt that a laboratory which confines its work to biochemical analyses and does not offer diagnostic advice could be directed effectively by a clinical chemist.

In addition to technical supervision, the director usually is in charge of staff hiring and overall finances; and if he is a pathologist, he often provides diagnostic advice to physicians using his laboratory.

Chief Technician or Senior Technician

Most laboratories which have more than four staff have an experienced technician who effectively runs the laboratory, supervises the other technicians, and usually is responsible for some purchasing, maintenance, quality control, and so on. In the laboratories in which the director pays only a brief daily (or less frequent) visit, it is the chief technician who is responsible for the quality of the work done. In the chains of laboratories he often is located in the main laboratory and pays frequent visits to the other laboratories, especially when they are having quality control or equipment trouble. The numbers in this group are included with technicians in the next section.

Technicians

The total technical staff employed in all laboratories is estimated to be 365. This includes 260 technicians in the non-specialized independent laboratories, eighty-nine in the chains of laboratories, and sixteen in the specialized laboratories. Sixty-eight per cent of the staff are female. Over half the technicians (59 per cent) are registered technicians; the remainder have a variety of qualifications from abroad, or no qualifications. Nine per cent have degrees (principally B.Sc.).

The estimated number of technicians in non-specialized independent laboratories is based on an average of 3.7 technicians per laboratory in the laboratories which answered our questionnaire. Qualifications and other data also are estimated for the total from the average data obtained in the answers. The true figures for all laboratories should be only slightly different.

It is very difficult to assess the quality of training of the unregistered technicians. Many are immigrants, particularly from central Europe and the Philippines, and have qualifications from their native countries. Some said that they worked in private laboratories because they had difficulty getting positions in hospitals, or because they felt that in hospitals they would not receive sufficient

credit for the training and experience they had acquired abroad. Only about 4 per cent are undergoing any current training. This small proportion appears to be attributable more to lack of educational facilities than to lack of interest.

It is impossible to make a valid comment on the quality of the work done by unqualified staff. During visits it was often thought that some of the staff were not of an acceptable standard. This assessment is largely subjective, however; and only an experienced technician would be able to confirm it, by examining the individual's technique.

In any laboratory employing a number of technicians, it is desirable to rotate the duties to keep interest and morale high. This is done in most hospital laboratories and in most private laboratories too; although where the staff is relatively inexperienced, rotation is impractical as it would be detrimental to the quality of the analyses.

Twenty per cent of the staff are employed part time for about twenty hours per week, and 6 per cent are part time for less than ten hours per week. This part-time group consists mainly of hospital technicians working overtime in evenings and married women working half days. Apart from those who have full-time hospital positions, some technicians work very long hours in private laboratories. It is estimated that about 5 per cent work over sixty hours per week.

Replies to the questionnaire showed that about half the technical staff were obtained by advertising and half by personal contact, often through the directors' hospital association.

About half of the laboratories were satisfied with the supply of staff and half were dissatisfied. This does not necessarily reflect the general staff shortage, since a private laboratory often can obtain hospital staff by offering more money. Although no detailed information was obtained on salaries, the author has reason to believe that private laboratory salaries for R.T.'s are generally slightly higher than hospital salaries.

About half the laboratories were satisfied with the quality of their new staff and half were dissatisfied. The average length of service of the technicians was about two years in training, plus three to four years in their present laboratory. Figures on the staff turnover are not very meaningful, however, since most of the laboratories have been formed in the last two or three years. We noted, though, that there is very little staff turnover in many of the smaller laboratories which are operated on a family basis.

Non-Technical Staff

Most laboratories have clerical staff and many have unqualified people to assist in washing glassware, and so on. Some employees whose principal duties are cleaning and washing are allowed to do some simple laboratory work. No information was gathered on non-technical staff.

Effect of Automation

Conventional biochemical analysis of blood usually involves the following sequence of operations: taking a sample, separation of the blood cells by centrifuging, addition of reagents, and measurement of some quantity (often colour) related to the concentration of the compound being measured. Most of these operations can be automated: a sample from a patient can be supplied to the autoanalyzer, which will then do all the necessary operations and even print out the results.

Most large hospital laboratories and some private laboratories are now automated, and it is generally recognized that these laboratories provide cheaper and more accurate analyses. It is difficult to predict the extent to which automation may be introduced in private laboratories, since the private laboratory normally does not have the advantage of being supplied with the large constant work load found in hospitals. Automated equipment is likely to be found principally in the larger commercial laboratories, particularly those with associated smaller "feeder" laboratories. It is doubtful if the small laboratory in a medical building or clinic will ever be able to justify this expense.

There will be a considerable change in staff requirements if automated equipment is introduced extensively into clinical laboratories. The skills required to set up and maintain an automated analyzer are quite different from those which are required to do manual laboratory analyses; and so, predictably, there will likely be a shortage of people competent to maintain the mechanical and electronic features of automated equipment. It is essential that plans to train technicians include training in this type of maintenance. The introduction of automated equipment will make many new demands on technicians It will require a high degree of integrity to reject analyses which do not meet the required quality control standards; if an analyzer goes out of control, it is costly to shut it down and possibly reject forty or more analyses. Since an automated laboratory will usually turn out 200 or 300 analyses per day, technicians must be completely familiar with quality control techniques. They must be trained through an intensive educational program, and they must work for conscientious senior technicians.

It is very unlikely that the introduction of automation will reduce the demand for technicians. A shortage is certain to exist at least in the foreseeable future. The laboratories were asked how the purchase of automated equipment would affect staffing. Eighty per cent replied that there would be no change; 10 per cent replied that the number of staff would increase; and 10 per cent that the staff would decrease. However, most laboratories appeared to be uncertain about how and to what extent automation would influence them.

About half the laboratories had plans to increase the number of staff in the immediate future to meet their general requirements.

Education

Present educational facilities for technicians in Ontario are generally recognized to be inadequate. A survey by Miss Naomi Grigg of the Ontario Hospital Services Commission indicates that there will be a shortage of about 1,800 technicians by 1970; the present rate at which technicians are being produced from the hospital training schools will not meet this shortage, or even meet the likely increase in demand.[1] Plans are under way for a Toronto Institute of Medical Technology to be opened in 1969. This institution should be given every support, for it will fulfil a very great need.

Many laboratories run training programs for their staff. It is impossible to judge how effective these are, although some are certainly highly organized and very helpful. These courses do not lead to any qualification, since they are not recognized by the CSLT or the CMA. The laboratories were asked if they would like to be provided with courses to which they could send their staff. Only 6 per cent were not interested, the vast majority being quite enthusiastic. Any refresher or other courses offered by an institute such as the Toronto Institute for Medical Technology would be very well supported and profitable in increasing the quality of private laboratory work.

A further educational problem which became apparent during our survey is the lack of contact which many laboratories have with modern methods of analysis and methods of quality control. There is a great need for some form of advisory service which can provide information and advice on the following questions:

1) Preferred methods of analysis and problems associated with analysis.
2) Problems associated with new equipment (the manufacturer is seldom to be believed completely).
3) Quality control methods (it is apparent that most laboratories have little concept of what quality control really means).
4) Kits and reagents (see p. 58).

When asked if they would like to have available such an advisory service, 96 per cent of the laboratories replied in the affirmative.

The author, therefore, finds that:

1) There is a need for the Government of Ontario, possibly through an organization such as the Toronto Institute of Medical Technology, to set up an advisory service on methods, equipment and quality control which is available to private clinical laboratories.
2) The existing educational facilities for laboratory technicians are inadequate for present and future needs. Any scheme to increase the output of technicians and attract more suitably qualified people to laboratory medicine merits active support.

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[1]Ontario Hospital Services Commission, Statistical Research Division, *Projected Need for Laboratory Technicians*, April 1966.

Chapter 4 Quantity of Services

The Present

Present estimates of the total amount of testing done by private laboratories in Ontario are given in Table 1. Also given for comparison are data on the total amount of testing done in hospital laboratories in Ontario and in Department of Health laboratories. In actual fact the figures for private testing are slightly higher than recorded. In the first place, some laboratories may not be included in our study; and second, several physicians do their own testing but are not classified as laboratories by our definition.

Unfortunately, no data exist on the growth of testing in recent years; but it has been estimated to be between 20 and 30 per cent per year. To accommodate the greater demand many new laboratories have been established. Undoubtedly there are a number of factors which contribute to this growth. Some are suggested below:

1) Medical insurance schemes now cover the cost of clinical tests in independent laboratories when these tests are deemed necessary by a physician. It is noteworthy that insurance schemes generally do not pay the physician for testing; thus he has little incentive to do the tests himself.
2) Previously the patient was usually confined to the hospital and tests were done by the hospital laboratory. But today, because of the shortage of hospital beds, the physician frequently treats the patient at home, using independent laboratory facilities for disease control. As more patients (for example, diabetics and leukemics) are treated at home, the strain on hospitals is relieved and more work is brought to independent laboratories.
3) Testing techniques have improved. New tests have been introduced, and automated procedures have in some cases reduced the cost and increased the quantity of testing.
4) There has been a steady population increase in Ontario, particularly in Toronto and other urban areas where the laboratories tend to be centred.

All available evidence suggests that the demand for clinical tests will continue o increase, new laboratories will be formed, and existing laboratories will be xpanded.

TABLE 1

Estimates of Clinical Testing Done Annually in Ontario, 1966

	Tests	DBS Units	Per Cent
Independent private laboratories	1,364,000	3,500,000[1]	6
Chains of private laboratories	556,000	1,400,000	2
Public health laboratories[2]	398,000	2,109,000	3
Hospital laboratories[3]		56,520,000	89
Total		63,529,000	100

The data in Table 1 suggest that private laboratories handle about 8 per cent of the total work load (it is impossible to calculate an exact figure without having a complete breakdown of the test types for hospitals). Several factors must be remembered in considering the proportion of testing done by private laboratories.

1) The DBS hospital units contain allowances for handling and procuring samples. This amounts to about 7 per cent of the total. The private laboratory figure does not contain such an allowance.
2) About 13 per cent of the hospital laboratory units consist of autopsy, surgical pathology, ECG, and EEG which either are not done by the private laboratory, or are not included in the private laboratory total.
3) Bacteriology and blood bank tests amount to about 27 per cent of the hospital total. These tests amount to a very small proportion of the private laboratory total.

It appears that only about 53 per cent of hospital laboratory work is of the type attempted by private laboratories. In the area of biochemistry, urinalysis and haematology, the private laboratories contribute between 12 and 15 per cent of the provincial total.

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[1]Estimated figure using a mean test number/DBS unit conversion.

[2]Clinical pathology specimens (55 per cent were blood sugar analyses).

[3]Includes inpatients and outpatients and referred-in work, but not work sent outside.

Note: Each test is assigned a number of DBS (Dominion Bureau of Statistics) units which is a measure of the amount of time involved in doing the test. One DBS unit represents about ten minutes of a technician's time. For example, a simple test such as glucose rates as two DBS units, while a more complicated, lengthy test such as ketosteroid analysis rates as fifteen units. The DBS units are currently under review.

The Future

It is difficult to estimate the future demand for laboratory testing. This will be affected considerably by the increased use of automated analyses and by possible subsequent alterations in the insurance payment structure. If the insurance companies were willing to pay lower rates for multi-screening tests, then it is almost certain that multi-screening tests would become quite popular. By these tests, for example, twenty analyses could be done for about thirty dollars, whereas at present the cost for individual analyses would be close to $100.

It is often suggested that the present demand for laboratory tests is much greater than the supply, and that the physician will make far greater use of multi-screening tests when these can be obtained at reasonable cost in a reasonable time. It seems likely that the multi-screening test will become a routine part of the annual physical check-up; but whether the test will be done by a private or a hospital laboratory, or in a special institution, is impossible to predict.

There is little doubt that the role of some private laboratories will change in the next two decades. The establishment of laboratories, under private or government control, providing multi-screening tests and possibly other physical examinations, coupled with a data processing system, may force other laboratories to alter the nature of their services. Expansion of hospital laboratories also may cause similar changes. However, the private laboratory likely will continue to play an important part in the country's health service. The scope of laboratory medicine is increasing; as it becomes possible to supply the physician with more data to aid diagnosis and therapy, and as the demand for such data grows, private laboratories will find it profitable to meet that demand.

Probably there will always be a need for the small laboratory which provides a very limited range of tests and is located in a medical building, particularly in areas remote from a hospital. This laboratory provides fast personal service with maximum physician-laboratory contact and minimum patient inconvenience.

A useful development would be the specialization of the larger commercial laboratories to provide large populations with, for example, steroid analyses, which are uneconomical when done in small quantities by a number of laboratories. Hospitals also could use these services, since at present some samples are sent to the United States for specialized analyses. The further specialization of laboratories will in many ways be analogous to the specialization of physicians' services.

It may well be that some laboratories will be developed privately where physical and chemical examinations will be handled by technicians using automated procedures. Such laboratories might be established by commercial organizations which are particularly reliant on the health of their employees. Many such organizations require routine medical examination for certain classes of em-

ployee, usually the higher levels of management. A laboratory which can give a physical examination at reasonable cost, in which the data are examined for patterns of abnormality by computer, and where further medical action can be recommended if necessary, will certainly provide a useful service to industry and commerce and should be correspondingly profitable.

Chapter 5 Quality of Services

Laboratory Errors and Quality Control

Implementation of a quality survey and interpretation of the results require a knowledge of statistics as applied to laboratory errors.[1]

When a sample is taken from a patient and analyzed for a substance, the result which the laboratory produces is generally different from the true value. The difference between the quoted value from the laboratory and the true value is the error. This error arises in a number of ways, including the following:

1) *Improperly Taken Sample.* The sample must be taken with the correct equipment. For example, a sample taken for enzyme analysis in a fluoride tube will give an erroneous result.

2) *Faulty Methods.* Most biochemical analyses can be done by several methods of varying reliability and difficulty. The selection of the method should be based on the individual laboratory capabilities. Faults of the method and possible interferences must be realized.

3) *Reagents of Incorrect Strength or Composition.* This is one of the most common errors and arises particularly with reagents which are unstable.

4) *Equipment Faults.* Glassware may not be of good quality and may not be clean. Instruments may not be checked and calibrated frequently enough; spectrophotometers with an aging light source can give erroneous results.

5) *Incorrect Technique.* Imprecise measurement of a quantity of sample or reagent will introduce a corresponding error.

6) *Special Sources of Error.* Many analyses must be done soon after the sample is taken. Some compounds such as bilirubin are light sensitive.

7) *Drug Interference.* Some drugs interfere with the analytical method — for example, mannitol with phosphorus analysis. Others alter

[1]In this section some statistical terminology is used which may not be familiar to some readers. Since we have not attempted a detailed explanation of statistical analyses, the reader wishing more information might consult "Quality Control in Clinical Chemistry", by Dr. D. B. Tonks, published by Warner-Chilcott. The booklet also provides a useful bibliography.

the normal blood analysis by pharmacologic effects — for example, codeine with amylase analysis. Certain foods also may interfere.

A competent laboratory director is aware of all these factors and takes precautions to avoid major errors. In addition, he should check the laboratory performance regularly by sending known (or control) samples through the analytical system, preferably without the knowledge of the technician. If this is impossible, it should at least be ensured that the technician does not know the true analysis of the control sample.

All laboratories have some form of quality control in operation, but these vary enormously in effectiveness.[2] There are two problems in implementing an effective quality control program. First, it is expensive. Second, many laboratory personnel are insufficiently trained to carry out the program and to interpret the results accurately. The usual method of assessing a laboratory's quality is for the laboratory director to provide, on a regular basis, samples of reconstituted serum obtained from one of the many commercial suppliers and have this analyzed in a routine manner in the laboratory. The comparison of the laboratory result with the manufacturer's stated analysis indicates the accuracy of the laboratory's operations. In a well-organized laboratory the results are recorded on quality control charts (provided free by the manufacturers of quality control products); the laboratory director thus can see at a glance any deterioration in accuracy and can correct it before the analysis goes out of control. Inaccuracy may be caused by faulty equipment or by a careless technician. Effective quality control procedure enables comparisons to be made between technicians.

We asked the laboratories to describe their quality control system. Most replied that they purchased quality control sera and ran these regularly with their samples, usually at least one control sample with each batch of analyses of a certain type. In many cases, however, we suspected that the thoroughness of the system was exaggerated. In returning the results of the analyses of our test sample, very few included the current standard deviation which we had requested. Apparently few laboratories understood what was meant by this.

We found, too, that there is an unfortunate tendency to believe that a quality control program consists of merely purchasing sera and running these occasionally to check the analyses. Quality control cannot be purchased in bottles. It requires further effort, not the least of which is the recording of day-to-day results on quality control charts. Only in this way can accuracy deterioration trends be detected. Few laboratories had quality control charts on display. Some of those which had charts entered one point each month.

Quality control is not obligatory but rather depends on the conscience of the director. All the laboratories we visited professed to be interested in it. Many take part in schemes organized from the United States and almost all were

[2]Dr. Tonks gives an excellent description of a quality control system. *Ibid.*

enthusiastic about the quality survey organized by the Committee. However, very few had adequate quality control procedures in comparison with, for example, large Toronto hospitals; and in several cases it was apparent that quality control was completely lacking. We suspect, too, that some laboratories simulated procedures for the benefit of the survey inspector and in fact do not always live up to their claims.

Generally, we feel that the problem is lack of knowledge rather than lack of interest. But the situation needs to be remedied, without delay. Quality control will become more important with increasing automation. It is sobering to realize the cost and risk incurred if an autoanalyzer is permitted to produce fifty incorrect analyses per hour. Only the application of careful and conscientious quality control procedures can prevent this from happening.

The Assessment of Laboratory Performance

The simplest method of assessing the performance of laboratories is to send samples for testing, the true analyses of which are known. In some studies, both accuracy and precision are estimated — as, for example, in the Tonks survey of 170 Canadian laboratories.[3] In this case, two samples are sent to each laboratory for testing. The results indicate not only the difference of the quoted values from the true values (i.e., the accuracy), but also errors caused by not following the method correctly (i.e., imprecise technique).

Lack of accuracy is not necessarily a serious fault, provided that the error is consistent and the precision good. A laboratory may consistently quote values 15 per cent high. But provided that the physician has all his analyses done at the same laboratory and provided that he learns to expect the laboratory to report high values, he can still detect changes in his patient's condition over a period of time; it is the *relative variation* in consecutive analyses that is important, rather than the absolute value.

The precision of laboratory analyses — as measured, for example, in the Tonks survey — can be misleading, in that the significant question is the ability of the laboratory to perform well *from day to day* rather than *on a single day*. The best method is to send samples regularly for testing. This has been done in the survey of Toronto hospitals by Dr. D. M. Young and Dr. C. J. Porter. If any provincial scheme is adopted for regular assessment of laboratory performance, it is advisable that a similar procedure be followed. A valid assessment of a laboratory's performance cannot be made on the basis of a "one-shot" analysis survey.

Time and resources did not permit us to make a detailed study of the performance of all the laboratories in Ontario. We were concerned rather with

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[3]Dr. D. B. Tonks, *Clinical Chemistry*, Vol. 9, No. 2, 1963, p. 217.

assessing accuracy alone.[4] Our method was to distribute a single sample to each laboratory and to request up to eight different analyses of the sample.

Unfortunately, only biochemical analyses could be submitted to the laboratories. To do a survey of other techniques, such as haematology or cytology, would have required professional medical personnel.[5] This was impossible in the present study, but if regular inspection is to form part of the licensing regulations for laboratories, it is essential that the inspectors be experts in these areas. (Alternatively, performance could be assessed by a pathologist or senior technician in the laboratory; but here there would be danger of a biased evaluation.)

From the results we obtained, the deviation of each quoted result from the "true" result can be found, and these can be combined to estimate the "between laboratory reproducibility" in the form of a standard deviation. This can be compared with standard deviations in other surveys, and the quantity of testing falling outside certain error limits can be calculated. The problem then arises of defining what the "true" value should be. There are three ways of doing this.

1) The mean of all the results can be assumed to be the true value. This will give an optimistically low estimate of the standard deviation.
2) Reference laboratories which are known for the high quality of their work can be asked to do the analysis and the mean of their results can be used as the true value.
3) It is possible to obtain commercial serum from which the materials to be analyzed have been completely removed by dialysis and to which quantities of the substances to be analyzed have then been weighed in accurately. The serum is freeze dried and sold in vials; it can later be reconstituted by adding water. The manufacturer supplies the assay values of the various components and these can be used as true value.

If the laboratories are allowed to add the water themselves to reconstitute freeze dried serum, the possibility of error is introduced through their not adding precisely the quantity required or not giving the serum sufficient time to dissolve. Alternatively, serum can be made up in advance for the laboratories, but it does not keep as well in liquid form and some of the substances (notably glucose) may deteriorate on standing. Refrigeration can minimize spoiling; and if samples can be distributed quickly, reconstituted serum tends to provide a more reliable quality test than freeze dried serum mixed in the laboratory.

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[4]We did not attempt to measure precision because in the terms of reference of the Committee, accuracy is a far more crucial factor in laboratory performance than precision.

[5]For example, tests involving microscopic examination of blood or tissue can be assessed only by a fully trained professional who can provide the technician with a number of slides and discuss them with him.

For our survey we obtained commercial freeze dried serum of known composition, reconstituted and bulked it, and split the bulked serum into samples which were refrigerated and delivered to the laboratories as soon as possible. In addition, samples were sent to reference laboratories, the Toronto General Hospital, the Toronto Western Hospital, and the Department of Health laboratory in Toronto, to confirm the manufacturer's assay values.

Quality Survey Procedure

The technique used in the survey was decided after studying the scientific literature and discussing techniques with several biochemists who are regarded as authorities in this area. There are three principal problems to be solved in preparation for a survey of this type.

1) Which analyses should be done?
2) What material should be analyzed?
3) How should samples be distributed? (Discussed also on p. 33.)

The following factors should be considered:

1) Preferably the analyses should have been done in other surveys so that comparisons can be made.
2) The substances to be analyzed should be reasonably stable to prevent erroneous results due to deterioration.
3) The analyses chosen should involve the use of as many different techniques and as many items of equipment in the laboratory as possible.
4) The analyses should be reasonably important in a clinical sense so that the laboratory will do them in a responsible manner.
5) At least one enzymatic analysis should be included.

No matter what group of analyses is selected there is bound to be criticism of the selection, in that the analyses will not meet all the above requirements. With careful compromise, the following analyses were selected: Glucose, Blood Urea Nitrogen (BUN), Sodium, Calcium, Phosphorus, Total Protein, Bilirubin, Transaminase (SGOT).

Some of these analyses involve special testing problems. Unless the analysis is done soon after reconstitution, glucose will partially deteriorate and a low result will be obtained. Bilirubin is sensitive to light, and unless precautions are taken to keep the sample reasonably dark, a low result will be obtained. Calcium may give anomalous results if the sample has been frozen and not properly mixed on thawing (this is thought to be due to stratification on freezing). SGOT, being an enzymatic analysis, must be done very quickly; therefore the SGOT sample was sent to the laboratories in the freeze dried form and they were asked to reconstitute it.

The laboratories were supplied with two samples. One was a 5 to 9 ml. sample of liquid serum on which they were asked to do the first seven analyses. The second was a vial of freeze dried serum which could be reconstituted to give 3 ml. of liquid and which they were asked to analyze for SGOT.

The serum for the first seven analyses was prepared by mixing reconstituted Versatol and Versatol A. This mixture has two advantages: the pattern of the analysis is not readily identifiable by the laboratory; and levels of the analyses are such that they all fall just outside of the normal range. The sample of SGOT was Versatol E.

A total of eighty-three samples of liquid serum and thirty-seven samples of SGOT were distributed. The usual precautions were taken in reconstituting the serum, distilled water being used and adequate time being allowed for the serum to dissolve. The vials were reconstituted separately and then bulked in five lots. The analyses of the five lots are given in Appendix II, along with the analyses obtained by the reference laboratories for these lots.

The samples were sent to laboratories as soon after preparation as possible. In the case of Toronto laboratories, the samples were sent by taxi on the day following reconstitution. Samples to other parts of Ontario were sent later, the serum being stored in a deep-freeze until it was dispatched. Some samples were delivered by hand at the same time as the inspection, but most were mailed by special delivery from Toronto. Check samples which received the same treatment as those that were mailed were sent to one reference laboratory; and no sample deterioration was detected, with the exception of one lot in which the glucose had deteriorated considerably. The glucose results from this lot were discounted. The samples were delivered to the laboratories with a detailed instruction sheet. The laboratories were asked to do only the analyses which they would normally do and to report the result, the method used, the normal range which they quoted for the result, and the current standard deviation for this analysis if it was known.

This method is open to the criticism that an unscrupulous laboratory could send the sample to another laboratory for analysis. As far as is known, no samples were referred to other laboratories. The technician who did the analyses was asked to sign the sheet, and this may have dissuaded laboratories from resorting to referral. The laboratories were generally very cooperative, eager to receive the samples and obtain information on how they rated in comparison with other laboratories. Many laboratories requested the true values, and these were supplied to them some months after the sample was delivered and the survey completed.

One laboratory accepted the sample only on condition that a representative of the Committee remained in the laboratory to see that the analysis was actually done in that laboratory. No laboratories refused to cooperate. No charge was made to the Committee for the analyses done.

Sample Distribution

One of our biggest problems was deciding how to distribute the samples to the laboratories in such a way that the results represented true day-to-day performance. Ideally the sample should be treated as routine, and the only way to ensure this is to provide a sample which the laboratory does not know is for a quality survey. The possibility of sending "blind" samples (i.e., samples of which the laboratory does not know the origin) was considered at length, and it was decided (for reasons discussed later) that this would be impracticable and in any event unnecessary. Accordingly, the samples sent to the laboratories were known to originate from the Committee's representatives; and distribution, analyses and reporting of results were done openly.

The fault of our method is that, since the laboratories knew that the sample was a quality survey sample, they probably gave it special treatment. One laboratory technician admitted that he did and said that he thought most others would too. The danger is that the survey measures not *typical* laboratory performance, but rather the *best* that the laboratories can do. Previous surveys[6] have suggested that usually the laboratory is unable to do very much better than its typical performance when presented with a quality survey sample. The reasons for this are that the principal errors in analyses are due to wrong technique, poorly calibrated instruments, reagents at the wrong concentration, poor glassware, and so on. These errors cannot be reduced without devoting a considerable amount of time to the survey analysis, and most laboratories are too busy to afford the effort. (The laboratories in our survey did not know when the sample was coming.)

Surveys have been made of hospital laboratories where it is easier to insert quality samples without the knowledge of the technicians. Weirberg and Barnett,[7] for example, supplied known and "blind" samples to a laboratory of a Connecticut hospital and compared the results for nine different analyses (four of them were the same as we asked for in our survey). In four of the analyses the known samples were done better, in four the "blind" samples were done better, and in one they were done equally well. It was concluded that: "In a study of 'blind' versus known quality control serums introduced into routine clinical chemical determinations no evidence was found that the analysts achieved a closer approach to the average known values, nor a narrower three standard deviation range for the known samples."[8]

In considering our results, then, it must be borne in mind that they probably represent the best that the laboratory can do. The average day-to-day performance of the laboratory presumably is slightly worse than is estimated here. Under

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[6]See, for example, M. S. Weirberg and R. N. Barnett, *American Journal of Clinical Pathology*, Vol. 38, 1962, p. 468.

[7]*Ibid.*

[8]*Ibid.*

adverse conditions when, for example, technicians are working overtime late at night or when they are working during periods of ill-health or stress, performance may be considerably lower. This is particularly likely in laboratories in which only one person is employed. Here there is no other professional on hand to check the work, and an individual may be doing analyses when his better judgement would dictate otherwise.

Periods of poor performance occur also because of staff shortage and because, to compensate for low wages, technicians frequently are forced to work overtime privately. It is not uncommon to find a technician working a seventy-hour week.

Whether or not accuracy should be measured by "blind" or "known" samples is an academic question, since it is almost impossible to introduce blind samples into private laboratories. The reason for this is that most laboratories insist on drawing the blood sample themselves. It would be possible to send a "blind" sample of blood to a laboratory with the collusion of a physician who is a regular customer of the laboratory, but this gives rise to two problems. First, blood is not stable, and there would be considerable uncertainty about the analysis of blood which may have been kept for several days. Second, in many cases the regular customers of the laboratory are also the owners; it is clearly unsatisfactory to ask a physician to submit a "blind" sample to a laboratory in which he has a financial interest.

Some laboratories were asked if they would object to receiving a "blind" sample. They generally replied that they would not object, but they thought that it would often be impossible to obtain the collusion of a physician.

Analytical Methods Used and Normal Ranges

Since there are a number of possible methods for doing each analysis, it is not always easy to interpret the results. For example, a glucose analysis can be done by at least six methods and the results generally vary. This difference is not important as long as the laboratory consistently uses the same method, particularly in testing samples from the same patient which are to be compared to follow the progress of treatment. In the case of glucose the Folin-Wu method will generally give a result 25 mg to 100 mg higher than the glucose oxidase method. Therefore, in analyzing the results, some allowance must be made for the method used. The technique used in this survey is described on page 72.

By performing a large number of analyses on a cross-section of the population, it is possible to define what is known as the normal range: it is the range within which the vast majority of the normal healthy population lie for a particular analysis. Normal ranges are frequently quoted in the medical literature, and they frequently differ. The normal range depends not only on the population, but also on the method used and the standard of analytical accuracy in the laboratory. The normal range for glucose by the Folin-Wu method is thus different from the normal range by the glucose oxidase method. Since it is possible for a laboratory

to report results which are consistently high or low, without realizing it, the normal range applied to that laboratory using its own method is not the same as the generally accepted normal range and a high proportion of its results will suggest misleading abnormality.

It is impossible for a private laboratory to make an independent estimate of its normal range, because it does not know which patients are healthy. The estimate must be left to government or hospital laboratories where information is available on both the analysis and the health of the individual. There is still a great deal of doubt about the true normal ranges of populations and much research remains to be done.

Criteria of Error Acceptability and Diagnostic Use of Analyses

If the object of a quality survey is to be able to say that a certain percentage of laboratory work is insufficiently accurate, then it is necessary to define the maximum acceptable error for each analysis. There are three criteria which can be used.

First, there is the Tonks criterion. Dr. D. B. Tonks of Montreal General Hospital has suggested that the error limits should be plus or minus one-quarter of the normal range for that particular analysis.[9] If the method used is not capable of giving this degree of precision, then the method should be abandoned. This criterion is generally regarded as setting too high a standard, especially in cases where the laboratory is under extreme pressure from a very high work load. It is almost impossible to maintain this standard unless the staff, equipment and reagents are of the highest quality. In addition, it is difficult to set the value of the true normal range. The criterion is thus one to be sought, but it is probably seldom attained.

Second, there is the error limit which the physician defines as acceptable. One possible definition of this is the point of error beyond which the physician feels he might medically mismanage a patient. The difficulty is that the result of the analysis is only a part of the information which comprises the physician's diagnosis; so that even if a result is highly erroneous, it does not necessarily mean that the patient will be medically mismanaged. Unfortunately there is no generally accepted definition of what the medical profession believes to be acceptable error limits for common biochemical analyses.

It is fairly certain that if there is any danger to the patient, little weight will be attached to one laboratory result. The laboratory result only *contributes* to the certainty of the physician's diagnosis; the extent of the contribution depends on the physician's training, his diagnostic skill, and the characteristics of the disease. In only a few serious illnesses does the patient's life depend on the laboratory result, and these analyses are done exclusively by hospitals. Inaccurate results are

[9]For the application of this criterion, see "Quality Control in Clinical Laboratories", *op. cit.*

thus more of a nuisance than a danger, although in exceptional circumstances a combination of faulty results and faulty diagnosis may endanger the patient. In any event, the sharing of responsibility by the physician and the hospital in no way reduces the responsibility of the laboratory to produce accurate results.

A third criterion of acceptability can be used. Information on the day-to-day accuracy of analyses can be obtained from a large number of hospital and private laboratories; thus a laboratory can compare its results with those of other laboratories. It seems reasonable that the laboratories which supply the most inaccurate analyses should be required to meet the standards of the better laboratories. In this way there would be a general improvement in laboratory performance. Repeated quality surveys would considerably assist the general upgrading; but the laboratory must, of course, be sufficiently interested in its own performance to work to improve it. The disadvantage of this criterion is that it does not reflect whether or not the analysis is acceptable to the physician. It provides merely a comparison between laboratories.

For most analyses normal ranges in the healthy population are well established; and the range of analytical error is approximately the same as the range of normal values. The Tonks criterion, that the error range should be one-half the normal range, is seldom achieved. The variance of results received by the physician from the healthy population is the sum of the normal range variance and the error variance, and is thus approximately twice the normal range variance. Consequently an analysis which is close to the normal range limit could be well inside or outside the normal range. Obviously, it is desirable to minimize the error variance and thus improve the information conveyed by the analysis. This will result in improved diagnosis with corresponding benefit to the population.

In cases where the disease results in very abnormal levels, the abnormality will be easily identified even with the usual analytical errors; therefore present analyses are acceptable for that disease. We conclude that the decision on the desirable level of error ultimately must be made by the physician, taking into consideration the individual disease, the importance which the analysis plays in the diagnosis, and the consequences of wrong diagnosis.

Discussion of Results

The results are given in detail in Appendix II in the form of the deviations of the results from the true assumed values. The mean deviation and the standard deviation were calculated, and the standard deviation is expressed as a percentage of the assumed value to give the coefficient of variation.

The laboratories were assured that their identity would not be revealed in the published results; accordingly, the results have been randomized. It would be misleading to draw any conclusions on the quality of a laboratory from one result. The results give only an overall estimate of quality in Ontario, which enables a

rough comparison to be made with other surveys and thus makes it possible to establish the quality of Ontario laboratories in relation to others.

The opinion has been expressed to the Committee that possibly as many as 2 per cent of the samples are wrongly identified — i.e., mixed with another sample. The present results show one mistake (Glucose 72 mg where the assumed value is 145 mg) and one wild sodium analysis which is attributable to its being done chemically instead of by the more reliable flame photometric method.

Appendix II gives the references to the other surveys, listed below, which can be compared with the present survey.

1) The survey of 170 Canadian hospitals by Tonks.
2) The survey of Toronto hospitals by Young and Porter.
3) The survey of New York State laboratories by the New York Department of Health.
4) The survey of United States laboratories by the College of American Pathologists.
5) The survey of United States small hospitals by the College of American Pathologists.
6) The survey of seven Canadian laboratories by the National Defence Medical Centre.
7) The survey of New Zealand laboratories by Desmond.
8) The survey of Australian laboratories by Hendry.

There are two possible ways of rating the performance of a group of laboratories as measured in a survey. The error characteristics can be expressed as a *standard deviation* or as a *coefficient of variation*. Essentially, the first measures the *absolute* error and the second the *percentage* error. Ideally, the laboratory group with the lowest standard deviation should also have the lowest coefficient of variation, but this does not always apply since the absolute levels of compounds to be analyzed may differ. An example illustrates this.

Survey A—True Value of samples is 200 SD is 16 C of V= 8%
Survey B—True Value of samples is 100 SD is 10 C of V=10%

It is impossible to state which group is better: on an absolute basis, B is better; on a percentage basis, A is better. This problem would not arise if all surveys were done at about the same levels, preferably close to the normal range.

The procedure in comparing this survey with others is to use *both* criteria. The detailed survey results are given in Tables 2 and 3, in which the standard deviations and coefficients of variation are given respectively. These data are represented in Table 4, in which the surveys are listed in "leagues" of performance, the best at the top. The position of this survey (outlined) gives an indication of the quality of Ontario private laboratories relative to others. Table 4 is discussed in detail below.

TABLE 2

Comparison of Survey Results

(Results Expressed As Standard Deviation)

SURVEY	Glucose	BUN	Calcium	Sodium	Protein	Phos-phorous	Bilirubin
This Survey	14.8	2.5	0.7	9.5	0.41	0.69	0.6
Tonks 170 Canadian Labs (2 Samples) Between Laboratory	Folin-Wu 9, 2 & 19.1	4.13	ND	13.8	0.63	0.63	ND
	Non-Folin-Wu 10.2 & 16.8	7.25		12.6	0.45	1.12	
Young and Porter Toronto Hospitals Average Within Laboratory S.D.	No Folin-Wu included 5.2	1.16	0.45	10.1	0.3	0.21	ND
Young and Porter Toronto Hospitals Deduced Between Laboratory S.D.	No Folin-Wu included 5.7	1.3	0.6	11.5	0.42	0.23	ND
New York State Dept. of Health	A. F. Wu 6.5 NF. Wu 5.3	2.1	0.6	9.2	ND	ND	ND
"A" Approved Labs "B" Unapproved Labs	B. F. Wu 11.7 NF. Wu 7.8	4.0	2.9	16.8	ND	ND	ND
Small Hospital Survey 1966 Coll. of American Pathologists U.S.A.	Folin-Wu 9.7	4.6	ND	ND	ND	ND	ND
	Non-Folin-Wu 8.1	6.1					
Nat. Comprehensive Lab. Survey Kit 1 Report Coll. of Amer. Path. U.S.A.	Folin-Wu 20.4 Non-Folin-Wu 19.9	7.3	0.94	11.7	ND	0.37	0.5
Desmond New Zealand Laboratories	7.6	4.2	0.57	6.1	ND	0.54	ND
Hendry Australian Laboratories	10.2	7.2	0.67	9.7	0.65	0.38	ND
National Defence Medical Centre Survey of 7 Canadian Labs	27	1.4	ND	7.8	0.39	ND	ND
UNITS	mg/100ml	mg/ 100ml	mg/ 100ml	mg/ 100ml	mg/ 100ml	mg/ 100ml	mg/ 100ml

ND—Not Determined.

TABLE 3

Comparison of Survey Results

(Results Expressed As Coefficient of Variation)

SURVEY	Glucose	BUN	Calcium	Sodium	Protein	Phos-phorous	Bilirubin
This Survey	10.2	11.9	8.0	3.2	7.0	11.5	26
Tonks 170 Canadian Labs (2 Samples) Between Laboratory	Folin-Wu 8.9 & 9.2 Non-Folin-Wu 8.7 & 12.1	23.1 31.6	ND	4.2 4.4	8.6 9.2	14.2 16.1	ND
Young and Porter Toronto Hospitals Average Within Laboratory C. of V.	No Folin-Wu Included 6.2	8.9	4.3	3.2	4.2	5.4	ND
Young and Porter Toronto Hospitals Deduced Between Laboratory C. of V.	No Folin-Wu Included 6.8	10.0	5.7	3.6	5.9	5.9	ND
New York State Dept. of Health "A" Approved Labs	A. F. Wu. 5.8 NF. Wu 5.0	13.8	6.1	2.9	ND	ND	ND
"B" Unapproved Labs	B. F. Wu 10.6 NF. Wu 7.4	28.2	29.0	5.3	ND	ND	ND
Small Hospital Survey 1966 Coll. of American Pathologists U.S.A.	Folin-Wu 8.1 Non-Folin-Wu 7.1	9.2 13.7	ND	ND	ND	ND	ND
Nat. Comprehensive Lab. Survey Kit 1 Report Coll. of Amer. Path. U.S.A.	Folin-Wu 6.4 Non-Folin-Wu 6.6	12.3	7.1	3.4	ND	13.8	22.7
Desmond New Zealand Laboratories	7.3	14.0	5.9	1.9	ND	16.2	ND
Hendry Australian Laboratories	RESULTS NOT AVAILABLE						
National Defence Medical Centre Survey of 7 Canadian Labs	15.3	4.1	ND	2.5	6.2	ND	ND

ND—Not Determined.

TABLE 4 — "Leagues" of Survey Results for Seven Analyses

[Arranged in order of increasing standard deviation (SD) and coefficient of variation (C of V)]

GLUCOSE		BUN		CALCIUM		SODIUM		PROTEIN		PHOSPHORUS		BILIRUBIN	
SD	C of V	SD	C of V	SD	C of V	SD	C of V	SD	C of V	SD	C of V	SD	C of V
Tor. Hosp. 5.7	N.Y.(A) 5.4	Tor. Hosp. 1.3	Nat. Def. 4.1	Tor. Hosp. 0.45	Tor. Hosp. 5.7	N.Z. 0.1	N.Z. 1.9	Nat. Def. 0.39	Tor. Hosp. 5.9	Tor. Hosp. 0.23	Tor. Hosp. 5.9	U.S. Labs 0.5	U.S. Labs 22.7
N.Y.(A) 5.9	U.S. Labs 6.5	Nat. Def. 1.4	Tor. Hosp. 10.0	N.Z. 0.57	N.Z. 5.9	Nat. Def. 7.8	Nat. Def. 2.5	**Present** 0.41	Nat. Def. 6.2	U.S. Labs 0.37	**Present** 11.5	**Present** 0.6	**Present** 26
N.Z. 7.6	Tor. Hosp. 6.8	N.Y.(A) 2.1	U.S. Hosp. 11.5	N.Y.(A) 0.6	N.Y.(A) 6.1	N.Y.(A) 9.2	N.Y.(A) 2.9	Tor. Hosp. 0.42	**Present** 7.0	Aust. 0.38	U.S. Labs 13.8		
U.S. Hosp. 8.9	N.Z. 7.3	**Present** 2.5	**Present** 11.9	Aust. 0.67	**Present** 8.0	**Present** 9.5	**Present** 3.2	Tonks 0.54	Tonks 8.9	N.Z. 0.54	Tonks 15.2		
N.Y.(B) 9.8	U.S. Hosp. 7.6	N.Y.(B) 2.9	U.S. Labs 12.3	**Present** 0.7	N.Y.(B) 29	Aust. 9.7	U.S. Labs 3.4	Aust. 0.65		**Present** 0.09	N.Z. 16.2		
Aust. 10.2	N.Y.(B) 9.0	N.Z. 4.2	N.Y.(A) 13.8	N.Y.(B) 2.9		Tor. Hosp. 11.5	Tor. Hosp. 3.6			Tonks 0.87			
Tonks 13.8	Tonks 9.7	U.S. Hosp. 5.3	N.Z. 14.0			Tonks 13.2	Tonks 4.3						
Present 14.8	**Present** 10.2	Tonks 5.7	Tonks 27.4			N.Y.(B) 16.8							
U.S. Labs 20.2	Nat. Def. 15.3	Aust. 7.2	N.Y.(B) 28.2										
Nat. Def. 27		U.S. Labs 7.3											

Abbreviations (See Appendix II for full references):

Tor. Hosp.—Toronto Hospitals.
N.Y. (A) —New York State Class A.
N.Y. (B) —New York State Class B.
N.Z. —New Zealand Labs.
Aust. —Australian Labs.
U.S. Hosp.—U.S. Small Hospital Survey.
U.S. Labs. —National Comprehensive Lab. Survey.
Nat. Def. —National Defence Medical Centre Survey.
Tonks —Tonks Survey of 170 Cdn. Labs.

"Present" refers to the survey undertaken for the Committee on the Healing Arts.

Glucose

The glucose results and their interpretation are subject to some doubt, since there was evidence that some samples had deteriorated before analysis. As this applied particularly to lots D and E, it was decided not to use any glucose results from these lot analyses. Similar trouble was encountered in the National Defence survey, which gave apparently poor results. The variation in method of glucose analysis also gives rise to a problem in interpretation; the method by which this complication is minimized is discussed in Appendix II.

The accuracy found in this survey was very low, being roughly comparable to that found by Tonks in 1960. If our results are reasonably representative of the actual accuracy, then private laboratories are providing an unsatisfactory service. It would appear (for reasons discussed later) that the performance is in fact somewhat better than our figures indicate, but there is obviously a great deal of room for improvement.

Blood Urea Nitrogen (BUN)

The laboratories fall roughly in the middle accuracy range for this analysis. They did considerably better than the Tonks survey indicated and fall between the Class A and Class B New York laboratories, suggesting that accuracy in Ontario is comparable to that in New York State. As in the case of glucose the Toronto hospitals are high on the list.

Calcium

The laboratories did reasonably well with calcium, being comparable to the New York State Class A laboratories in accuracy.

Sodium

Sodium analyses were done by comparatively few laboratories. The accuracy appears to be about average and, surprisingly, better than the Toronto hospitals on average. Again the accuracy was better than found by Tonks.

Protein

The private laboratories did fairly well, apparently being about equivalent to the Toronto hospitals generally and better than was found by Tonks. In both protein and sodium, the larger well-equipped Toronto hospitals which process a large number of samples per day are significantly better than the private laboratories.

Phosphorus

The accuracy was about average, again being better than found by Tonks.

Bilirubin

One other survey used bilirubin analysis and its results were slightly better than found in this survey.

SGOT

The SGOT results were reasonably satisfactory, in that all the laboratories found abnormality in the sample. A value of greater than forty units is regarded as abnormal, the assumed values in the samples being about 300. The distribution of results is given below:

Range	0 to 40	40 to 100	100 to 200	200 to 300	over 300
Number	0	1	3	8	14

Only one laboratory was below 170 (actual value 70) and this was possibly a mistake in identification. No data are available to compare the performance with other laboratories. The general level of accuracy, however, is low—the four results below 200 units being less than satisfactory.

General Findings

Excepting glucose analyses, the performance of Ontario private laboratories can be summarized as follows:

1) The accuracy is significantly better than was found in Tonks' survey of Canadian laboratories in 1960.
2) The accuracy is slightly poorer than the New York State Class A (approved) laboratories but significantly better than the Class B (unapproved) laboratories.
3) The accuracy is generally comparable with or inferior to the average accuracy of Toronto hospitals, and definitely inferior to the accuracy of the larger well-equipped, well-staffed hospitals.

The disagreement between the glucose results and the others suggests that either, for some reason, glucose analyses are done particularly badly in private laboratories in Ontario; or the survey was at fault in not providing good samples.

Therefore, our study finds that:

4) There is no cause for alarm at the level of accuracy at which Ontario laboratories are performing; and it is not true to suggest that the laboratories are providing an inferior service, with a high percentage of erroneous results which lead to patient suffering. The laboratories are providing a responsible, medically useful service, comparable to that provided elsewhere.
5) Bearing in mind that the level of accuracy as measured in this survey is probably the best that the laboratories can do and that

> at times the level of accuracy may be much lower, it is apparent that there is room for and a need for improvement. Action should be taken to effect such an improvement.

The results are generally better than those obtained in the Tonks survey, and it is not clear why this should be so. Tonks found 40 per cent of the results to be unacceptable by his standards. If these standards are applied to this survey using the same analyses, the percentage of unacceptable results is about 30. This is a very strict criterion of acceptability, and it is doubtful if many laboratories are able to operate within the criterion limits of allowable error.

Chapter 6 Specialized Laboratories

The laboratories which we have discussed so far do mainly biochemical and haematological tests. Some of them may provide a number of specialized services as well. In this section we consider other laboratories which provide specialized services only.

Cyto-Pathology Laboratories

There are four laboratories in Ontario which specialize in cyto-pathology. These are staffed by trained cytology technicians working under the direct medical supervision of pathologists. Since the field is highly specialized, and thus is not amenable to common methods of quality control, we cannot comment here on the reliability of these laboratories. The only means of assessment would be inspection by a pathologist and possibly some form of follow-up program.

The principal service offered by cyto-pathology laboratories is the screening of vaginal smears, a service which is provided also by hospitals and Department of Health laboratories. The fee charged for the test is that laid down in the OMA Schedule of Fees. One laboratory director suggested that the fee was too high, and that a reasonably efficient laboratory with a high turnover could easily operate at a considerably lower fee.

The largest laboratory, Cyto-Pathology Associates, employs fifteen pathologists and nine technicians. The pathologists all work part time.

Radio-Isotope Laboratories

There is one laboratory in Ontario which offers radio-isotope services only (some other laboratories offer radio-isotope services in addition to other more common services). Before a laboratory can perform in this area, an Atomic Energy Commission licence has to be obtained. Since the equipment is expensive and interpretation of results is very specialized, radio-isotope laboratories must be run by highly competent people. Again, though, we were unable to assess the actual performance of these laboratories.

Electrocardiograph Laboratories

The electrocardiograph is now a fairly common piece of laboratory equipment; and since it costs just over $1,000 it is well within reach of the average laboratory or clinic. In our study we found that about half of the laboratories had electrocardiographs, and we encountered no laboratories which did electrocardiograph

work only. Several laboratories employ consultant cardiologists to interpret results; but in most cases they merely obtain the traces and send them to the physician, who then obtains an interpretation from the cardiologist.

Electroencephalograph Laboratories

The taking of an EEG involves measurement of electrical activity in the vicinity of the brain, to detect abnormalities in brain functioning. The traces obtained usually are interpreted by a neurologist. Since this is a very specialized procedure, the people who perform it must be fully qualified; a physician will refer a patient only to an EEG laboratory directed by a neurologist. We encountered a number of EEG laboratories in Ontario, but we obtained no data from them.

Pregnancy Test Laboratory

This laboratory is run by pharmacists and receives most of its samples from drug stores. There is no medical supervision.

Allergy Laboratory

Under the direction of a specialist, the laboratory supplies allergenic extracts for diagnosis and treatment of allergic respiratory disorders. The director has had continuing discussions with the Federal Food and Drug Directorate regarding licensing of such laboratories. The laboratory was not visited.

Renal Laboratories

These laboratories specialize in the analysis of material associated with kidney disorders including kidney stones. They are under medical direction.

Specialized laboratories present problems for licensing and regulation. Care will have to be taken that legislation introduced to cover the common clinical laboratory does not interfere with or unnecessarily restrict their performance.

Chapter 7 Licensing and Regulation

Existing Legislation in Ontario

At present anyone can set up a clinical laboratory in Ontario for commercial testing. No licence is required, and there is no regulation or inspection. The standard of work is entirely at the discretion of the director.

Bill 71 (1967) amends the Public Health Act, making provision for licensing and regulation; and although it has been reported that the Government of Ontario plans to introduce licensing and regulation, procedural details and dates have not been announced. The relevant amendments to the Act are as follows:

Addition of paragraph 43 to Section 6—

> 43 (1) No person shall operate a health facility of any class prescribed by the regulations made under paragraph 31 of Section 6 without a license therefor.
>
> (2) No person shall operate or be engaged in a health facility of any class prescribed by the regulations made under paragraph 31 of Section 6 without being qualified as required by the regulations.

Paragraph 31 of Section 6 referred to above defines health facilities as follows:

> Designated classes of public health and medical laboratories, radiological clinics for diagnosis and therapy, prosthetic and orthotic establishments and such other classes of health facilities as the regulations may designate.

It is generally agreed that the present position in Ontario is unsatisfactory. It seems unreasonable that a totally unqualified person should be able to practise laboratory medicine, thereby possibly endangering the health of the public. The main problem facing the Government of Ontario at present is not whether there should or should not be licensing and regulation of laboratories, but who should administer the licensing and regulation. In addition, there is no obvious licensing procedure which is acceptable to all parties involved in running clinical laboratories. Even within the medical profession there are marked differences of opinion as to how licensing and regulation should be implemented.

The College of Physicians and Surgeons of Ontario has clearly stated its position on the need for control of diagnostic laboratories, as follows:

> *Need for Control of Diagnostic Laboratories*
>
> As medical insurance plans extended their benefits to include diagnostic laboratory procedures, there has been a marked increase in the number of private laboratories established for the purpose of providing radiological and pathological services.

The radiological laboratories, so far as we know, are under the control of qualified medical practitioners, and technical personnel come under the provisions of The Radiological Technicians Act (1963).

However, in the absence of controlling legislation and inspection procedures, it has been possible for bacteriological, biochemical and haematological diagnostic tests to be carried out for profit without qualified supervision.

The College can take no exception to a diagnostic laboratory under the control of a qualified biochemist or bacteriologist performing chemical, biochemical or bacteriological tests on human material. It is, however, seriously concerned where these tests are carried out by a technician who is not under the control and supervision of such a suitably qualified person. Unless the diagnostic laboratory is under suitable control there can be no assurance that adequate measures are being taken to ensure the accuracy of their analytical results. Inaccurate calibration of the diagnostic apparatus, undetected deterioration of the test reagents of inferior quality, can occur in a laboratory under unqualified and inadequate supervision.

Where a diagnosis is to be made on the basis of examination of human specimens or tissues, it would be dangerous and illegal for this interpretation to be given by other than a suitably qualified medical practitioner. The proliferation of privately operated diagnostic laboratories, and the rather widely advertised services such as pregnancy tests and blood counts, contain such elements of risk to the public that the College strongly recommends institution of a provincial system for the inspection and control of diagnostic laboratories.[1]

Licensing Outside Ontario

Regulation of laboratories is a problem which is not peculiar to Ontario, and steps have been taken to implement licensing in other provinces and in the United States. The forms which licensing has taken in these places are discussed in this section.

Clinical laboratory licensing already exists in a number of states in the U.S.A., notably New York, California and Illinois.[2] The laboratory is given a licence if it meets a number of requirements, including the following:

1) The laboratory director and his staff must have suitable qualifications and experience.
2) The laboratory facilities must be inspected and found to be up to the standard required in the legislation.
3) The laboratory may be required to cooperate in a system of quality control administered by the State Department of Health.

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[1]Brief of the College of Physicians and Surgeons of Ontario to the Committee on the Healing Arts, Part II, p. 11.

[2]As of December 1967, laws setting forth requirements for independent laboratories existed in nineteen states, plus the District of Columbia and Puerto Rico. See *Lab World,* Vol. 19, No. 1, January 1968, p. 36.

4) There is a restriction on the number of laboratories (usually two) which can be directed by one person.

The legislation includes the power to discipline the laboratory if it fails to meet the requirements. The laboratory can be closed at the discretion of the State Department of Health.

Many other states are contemplating the introduction of legislation; and to assist them, the National Communicable Disease Center in Atlanta, Georgia has produced draft enabling legislation which serves as a model for new legislation. However, the detailed regulations of, for example, the director's qualifications are not suggested, since these should reflect local conditions.

In Canada, Alberta has introduced legislation to license clinical laboratories through the authority of the Royal College of Physicians and Surgeons of Alberta. Thus the licensing of laboratories is analogous to the licensing of physicians to practise medicine.

The situation in Quebec is complicated by current changes in medical insurance in Quebec. It appears that the Quebec government prefers to do without clinical laboratories organized on a private commercial basis and intends to rely entirely on hospital laboratories.

The experience of other licensing authorities is valuable in deciding on the Ontario form. However, no single licensing scheme has been found to be ideal, and it appears that a period of trial and transition is still ahead.

The procedure adopted by Ontario will be examined with great interest by many governments both within and outside Canada. On several occasions the opinion was expressed to the author that if Ontario succeeds in developing a licensing scheme different from, and superior to, existing schemes, then other governments will adopt similar schemes. The Government of Ontario has here an opportunity to provide leadership in the licensing of laboratory medicine; and it is therefore important that the licensing authorities weigh carefully the merits and demerits of existing and proposed schemes.

The Ontario Medical Association Accreditation Scheme

Recognizing that there exists a potential hazard to the public through poor quality clinical testing, in 1966 the OMA set up a special committee to study the problem. The committee has developed a voluntary accreditation scheme, which started in mid-1967. At the time of writing, the coverage of laboratories by the accreditation scheme was far from complete.

The scheme operates as follows. The laboratory is visited by a group of pathologists, who complete a questionnaire which seeks to establish the ownership of the laboratory, the laboratory's facilities, the qualifications and experience of the director and his staff, and the form of quality control which is practised

by the laboratory. The questionnaire is very searching; and there is little doubt that through this kind of examination a complete picture is gained of the laboratory's organization. The scheme suffers from two drawbacks. First, because it is voluntary, only those laboratories which are sufficiently interested in having their standards assessed and compared with other laboratories have so far been visited. Second, because the members of the accreditation committee have difficulty in finding time to devote to this scheme, progress has been slow.

The OMA believes that since laboratory work is a branch of medical practice, it must be supervised by qualified and licensed medical practitioners. Any sanctions to be imposed on unsatisfactory laboratories should be administered internally by the medical profession. The OMA would thus favour Ontario legislation similar to that adopted in Alberta.

The claim that a physician should supervise a laboratory is open to the criticism that a physician has little formal chemical training—even pathologists are not necessarily well trained in biochemical analysis. Nor can it be assumed that laboratory work is a branch of medical practice, unless the scope of "medical practice" is defined. If medical practice is defined as diagnosis and therapy, then most laboratories cannot be included, since they do not diagnose but merely provide analyses which *lead to* diagnosis.

We note, however, that the OMA Section on Clinical Pathology has acquired considerable experience in questioning laboratories, and we recommend that this experience be exploited fully by the agency which ultimately licenses clinical laboratories.

The Canadian Medical Association Scheme for Approval of Training Programs in Medical Laboratory Technology

In 1964 the CMA Committee on Approval of Training Programs in Medical Laboratory Technology set up a subcommittee on standards. This subcommittee was asked to recommend the method by which the committee could assess the training programs and the criteria which it should use in this assessment. A scheme eventually was devised which has proved very effective in assessing the standard of these teaching laboratories and also in improving laboratories which do not meet the required standard.

The assessment of hospital technician training programs may at first sight appear to be quite different from the assessment of private clinical laboratories. However, on further consideration it appears that there are important similarities, and much can be learned from the CMA experience. The CMA has developed an effective multidiscipline mechanism for inspecting these programs which has achieved a high degree of cooperation between the various interested groups. The scheme is conceived not as a means of closing down centres which are unsatisfactory, but rather as a means of defining inadequacies and raising standards to the required level.

A modified revision of the CMA scheme could be developed for private laboratories which would have a considerable advantage over existing schemes, for example, in Alberta or New York. The CMA scheme is described in some detail below.

After some preliminary correspondence between the CMA committee and the hospital administration, arrangements are made for a survey party to visit the hospital. This preliminary correspondence includes the supply to the hospital administration of copies of the "Basis of Approval of Programs for Training Medical Laboratory Technologists" and copies of previous survey reports. This enables the administration to become totally familiar with the procedures involved and the standards required. In addition information is obtained from the Canadian Society of Laboratory Technologists on the number of students who have been trained in the hospital and their examination results.

A survey party is then formed from representatives of relevant organizations, including

The Canadian Medical Association (Chairman)

The Canadian Society of Laboratory Technologists

The Canadian Society of Clinical Chemists

The Canadian Association of Medical Bacteriologists

The Hospital Association of the Province.

The party then visits the hospital, and inspects the facilities and training procedures. A draft report, which is prepared by the surveyor, is circulated to the party and altered as necessary; and a final report is sent to the hospital administration recommending any changes thought necessary. A survey team will usually visit a number of hospitals on one trip; and arrangements are made to revisit hospitals on a regular basis, the frequency being determined by the rate of change of circumstances.

The scheme has been remarkably successful in the degree of unanimity which has been achieved among the members of the survey party in the features requiring improvement. Close liaison has developed among the associations involved —a marked and pleasant contrast to the usual bickering between professional groups on the fringe of the medical profession. Moreover, while it has provoked remarkably little controversy, the scheme has brought an improvement in the existing training programs.

One excellent feature of the scheme is that groups of experienced persons have been established in each of the professional societies, so that there is little strain on the manpower resources of each society when new groups are formed.

The success of the CMA scheme in improving hospital training facilities makes it worthy of consideration as a basis for inspecting private clinical laboratories.

Also, a private laboratory scheme based on the CMA scheme would have the outstanding merit of bringing together the professional groups involved without risking the dominance of one professional group over another.

Attitude of Laboratories

The laboratories were asked their attitude to government licensing. Only 4 per cent were opposed. Fifteen per cent were non-committal, and this included groups who were unwilling to state an opinion until the form of licensing was more closely defined. The remaining 81 per cent welcomed government licensing. Second, the laboratories were asked what their attitude would be to regular government inspection. Again, only 4 per cent opposed inspection. Four per cent were non-committal, and 92 per cent welcomed inspection. Third, they were asked what their attitude would be to a government quality control scheme, this being interpreted as a scheme by which known samples would be sent to the laboratory for analysis and the laboratory would then be able to compare its performance with others. Ninety per cent of the laboratories welcomed such a scheme and the remainder were non-committal.

It is encouraging that most laboratory directors wished to be provided with some scheme by which the performance of their laboratory could be compared with that of others. Ninety-six per cent also favoured a voluntary government advisory service on methods and quality control. It appears that while there is room for improvement in the quality of laboratory work in Ontario, some laboratories definitely want to improve their accuracy. The scheme which eventually is introduced should take advantage of this attitude.

Discussion of Licensing and Regulation

Inevitably the first question to be answered is: Is licensing desirable? For the following reasons, the answer is undoubtedly "yes":

1) A situation where a totally unqualified person can set up a commercial laboratory is hazardous.
2) The medical profession, which constitutes the laboratories' customers, favours some form of licensing.
3) The majority of laboratories themselves favour licensing.
4) The accuracy of laboratory work in Ontario is adequate but must be improved. This can be done only by the intervention of an outside agency which both restricts and educates.

We thus conclude that there is a need for licensing and regulation. The problem remains of deciding who should do it and how.

In the following discussion of the form which licensing and regulation should take in Ontario, the least controversial aspects are considered first.

Qualification of Licensing Personnel

It is essential that the licensing authorities be persons fully trained and experienced in the classes of work done by the laboratory. One person alone cannot acquire the expertise necessary for assessing laboratory performance in all its departments. For example, only a pathologist experienced in cytology can assess whether a cytology technician meets the required standard. Therefore inspection must be done by a group of people of differing experience and qualifications. It is assumed here that the initial licensing will include an inspection, as it is impossible to form an opinion of laboratory performance without observing the laboratory in operation.

Scope of the Licence

The laboratory licence must define the classes of testing which the laboratory is competent to do. No single laboratory can perform all the tests which are listed in the OMA Schedule of Fees, and very few are equipped to do more than thirty simple tests. It would be a mistake to require that a laboratory be competent to do a comprehensive range of tests, since this would eliminate a number of small laboratories which are interested in doing only the more common biochemical and haematological tests. Such laboratories of limited scope can provide an excellent, fast service, particularly in rural areas remote from hospital laboratories with comprehensive facilities. As circumstances in the laboratory change, the licensing authority should be advised and the licence may as a result be changed to include or exclude certain types of tests. Any changes must, of course, be related to the skill of the laboratory personnel to do these tests. OMSIP has already established a system whereby certain laboratories will not be paid for doing certain types of tests which OMSIP does not consider they are competent to do.

Regular Inspection and Quality Survey

There must be some form of continuing contact between the licensing authority and the laboratory, with inspection at regular intervals. A laboratory faced with the prospect of an inspection naturally will put its house in order for the occasion. Therefore, if the object is to evaluate laboratory performance as it exists from day to day, it will be essential to inspect the laboratory at regular intervals with little or no warning. In addition there should be a parallel quality control scheme running continuously for all laboratories. This will give the licensing authority some quantitative data on the laboratory and give a factual record of the laboratory's performance, including any deterioration or improvement. It will also help to avoid any personal influence coming to bear on the authorities' licensing decision.

In the future other quality survey methods may be used which do not involve submitting samples for analysis. For example, if the laboratory reports *all* its results to a central computing agency, the existence of bias or unacceptably large errors can be detected by statistical techniques, provided data exist on the normal ranges of the population using private laboratories.

Disciplinary Powers

The legislation must, of course, contain provision to remove the licence if a laboratory does not meet the required standard, but in addition it must provide penalties under law if the laboratory should operate without the licence. Since the government will ultimately impose these penalties, it seems reasonable that the government should have the authority to issue licences.

Who Should License?

The principal point of contention arises in deciding who should be the licensing and regulating authority. Should it be a government department or a specially constituted commission, or should authority be invested in a medical organization such as the College of Physicians and Surgeons or the Ontario Medical Association? This question is closely related to the problem of deciding who the inspection group should be. Presumably, if authority is given to the OMA, the inspectors will be physicians and pathologists in the OMA. If authority is given to the Department of Health, then the inspectors could be either employees of the department or possibly members of professional organizations called upon from outside the department specifically for this purpose. A special commission could request cooperation from professional groups and the Department of Health. The following section discusses relative merits of these approaches, particularly as they may be employed in Ontario.

Licensing by the Medical Profession

Handing over control of licensing to a medical body (as has been done in Alberta) is probably the simplest procedure from a legislative point of view. The medical profession has at present some control over clinical laboratories, in that the insurance schemes require a licensed physician to be director of the laboratory; but although it is generally accepted in the medical profession that there are unsatisfactory laboratories in operation in Ontario, no effort has been made to close down these laboratories by disciplining the physicians involved. As far as is known, the titular directors have never been subjected to any pressure from the OMA or the College of Physicians and Surgeons.

There is a potential risk involved in giving authority to a medical organization: those in the position of authority will tend to be pathologists at present working in large, well-equipped, efficient hospital laboratories; if they seek to impose the same standards of quality, staff qualifications, equipment, and so on as exist in some of the larger hospitals, then many clinical laboratories will be closed immediately. This will result in an unnecessary reduction of clinical laboratory services at a time when there is a demand for further expansion.

Another argument frequently cited by non-medical personnel is that the medical profession is not generally qualified to assess the accuracy of biochemical analyses, which constitute the principal work load in most clinical laboratories.

Certainly a physician with no laboratory training is not qualified to run a clinical laboratory. There is also a fear among non-medical professional groups — notably clinical chemists — that, if control were given to the medical profession, they would be prevented from setting up laboratories.

In view of these objections, we conclude that it is undesirable to give authority to license exclusively to the medical profession through one of its professional organizations.

Licensing by a Government Department

If licensing is going to be administered by a government department, there must be some formal regulations on acceptable standards. Establishing such regulations involves formidable problems.

In Ontario a large proportion of the staff in private clinical laboratories has been trained in Europe. The qualifications of many of these people (by North American standards) are questionable; but at the same time it is impossible to specify minimum acceptable qualifications which include this wide variety of backgrounds.

The regulations will have to be flexible to provide satisfactory control over a wide variety of laboratories attempting different types of analyses, including the specialized laboratories discussed in Chapter 6. This flexibility will inevitably introduce an unsatisfactory element of looseness in the regulations. The problem is further complicated by the fact that the pattern of work in clinical laboratories will probably change markedly in the next decade with the introduction of auto-analysers and multi-screening tests. Undoubtedly the next few decades will see a revolution in laboratory medicine, and it would be a great pity if this were hindered in any way by restrictive legislation.

The problem is to introduce legislation which will be effective in preventing unethical enterprise, without interfering with ethical enterprise, and which at the same time will remain flexible enough to accommodate future changes in laboratory medicine.

The government agency scheme has been shown to work, to some extent, in the United States. There it has effectively eliminated unethical laboratories; but it has been generally unsuccessful in raising the standards of existing laboratories through programs of education. It would be fairly easy for the Department of Health to rewrite United States' regulations in a form suitable for Ontario. A new section could be created in the Department of Health, using the existing facilities of the Public Health laboratories; this section would necessarily have access to the services of experienced biochemists, haematologists, cytologists, bacteriologists, microbiologists, and so on.

If control were given to the Department of Health, however, a conflict of interests may arise. The Department competes with private laboratories in some

areas of biochemistry where the Public Health laboratories perform some of the same tests for private physicians as do the private laboratories and offer a free blood sugar testing service. It seems unwise to give control exclusively to a group in competition with private laboratories, and the laboratories certainly would be alarmed (with some justification) at such a move. Such conflict of interests could be avoided by including a strong impartial element in the licensing authority.

Licensing by a Special Commission

For the reasons given above, the authority preferably should be a specially constituted independent body of disinterested people who can call upon professional cooperation from both the Department of Health and professional organizations. It is beyond the scope of this report to recommend the exact constitution of this body, but it is worthwhile considering the methods which this body should use in assessing laboratories.

A method based on the CMA scheme described earlier has obvious advantages over any other. The great merit of this scheme is that it would involve the Canadian Society of Clinical Chemists, the Canadian Society of Laboratory Technologists and other professional organizations — all of whom are very much concerned about the standard of clinical laboratories, and all of whom have shown their competence and willingness to cooperate with the medical profession in creating effective survey teams for inspection purposes. Any system which can bring together the various groups involved in clinical laboratory work and which can provide a format for these disciplines and skills to work together harmoniously to improve the standard of clinical laboratories is worthy of very serious consideration.

A method based on the CMA scheme has the disadvantage that to date it has not been tested in any North American province or state as a system for licensing private clinical laboratories, and there is thus no evidence that it will succeed. CMA experience has shown, however, that such a scheme would almost certainly be effective.

The ideal licensing and regulating system is not necessarily the one which will will be implemented: economic considerations may dictate that a less effective scheme be adopted. When the new organization is set up, it must be borne in mind that private laboratories do a relatively small proportion of the total testing in Ontario.

Insurance already plays an important role in private laboratory economics; and with the introduction of medicare, this role would become even more important. Usually it is desirable to give the insurer a voice in the licensing body; OMSIP, for example, already has considerable information on laboratories and their capabilities.

Summary

Having studied the various forms of licensing and having discussed the issue with a number of interested parties in Ontario, we come to the following conclusions.

The most effective scheme for licensing and regulating private clinical laboratories is one in which the licensing authority is a specially commissioned body, consisting of impartial lay persons and representatives of the Department of Health, which will act on the advice of representatives of professional organizations interested in laboratory medicine.

The licensing authority can obtain its factual information on laboratories most effectively by inspection and by continuing quality surveys.

1) Inspection

The preferred inspection scheme is one based on a modification of that used in the Canadian Medical Association Scheme for Approval of Training Programs in Medical Laboratory Technology as outlined below. Inspection should be carried out by a survey team constituted of members from the following organizations:

The Department of Health

The Ontario Medical Association

The Canadian Society of Clinical Chemists

The Canadian Society of Laboratory Technologists

The Canadian Association of Medical Bacteriologists

(Any other relevant organization).

Other professional groups could possibly be included as the need arises. Laboratories should be provided well in advance with statements of procedures and minimum specifications required. The survey group should be supplied with the necessary information on staff qualifications and on the laboratory performance in quality surveys. After inspection, a report should be drawn up and agreed upon, and recommendations made to the licensing authority as to the licence to be awarded. Any changes in the technical staff of the laboratory should be reported immediately. There should also be a less formal, unannounced inspection at fairly regular intervals. The survey team should visit the laboratory once every two years, or more frequently if necessary. The representatives of the organizations constituting the survey team should be paid an appropriate consulting fee. The authority should make full use of the experience of the Canadian Medical Association and the Ontario Medical Association in drafting the scheme outlined above.

2) Quality Survey

The laboratory should be required to cooperate in a continuing program to assess the accuracy of its analyses. The results of this program should be made available to the laboratory to enable it to compare its performance with that of other laboratories in Ontario.

The Wider Problem

This report is concerned exclusively with private laboratories; however, in discussing licensing and in recommending licensing procedures, we can extend these procedures to include other laboratories. At present hospital laboratories receive only cursory inspection as part of the wider inspection by the Ontario Hospital Services Commission. Many small hospital laboratories probably would benefit from inspection and advice similar to that proposed for private laboratories. Although they are exempt from being in the extreme unethical class in which it is occasionally claimed some private laboratories fall, there is no reason to suppose that hospital laboratories are on the whole more efficient than private laboratories. It might even be profitable to inspect Public Health laboratories to gain information on their standards, and to relate these to hospital and private laboratories. A continuing quality survey which included these types of laboratories would be very interesting and valuable. Obviously, the hospital and Public Health laboratories cannot be "licensed" in the same way as private laboratories, but they could be subject to official approval. Accordingly, we suggest that:

> Since private laboratories provide a relatively small proportion of the medical laboratory services in Ontario, and in view of the growth of laboratory medicine, it may be desirable to set up an organization to regulate *all* medical laboratories, including private, hospital and Public Health laboratories.

Comments on Minimum Standards

It is not the object of this report to define the minimum standards which a laboratory should meet. When we discussed the problems of private laboratories, a number of requirements were suggested; some of these are listed below with comments.

Qualifications of Director

A physician with no special laboratory training is not well qualified to direct a clinical laboratory doing comprehensive tests; usually his training in chemistry is weak. Often the only justification for his being a director is that he can be expected to direct an ethical organization. Clinical chemists are qualified to direct a laboratory which supplies no interpretation or diagnostic service. Only a clinical pathologist with chemical training can direct a comprehensive laboratory with a diagnostic service.

Qualifications of Staff

It would be unnecessarily restrictive to require that only R.T.'s be employed. If suitable training programs are made available to experienced non-R.T.'s, which enable them to become qualified with the CSLT, then it may be possible to set a time limit after which CSLT qualification will be required of staff working in medical laboratories.

Extent of Direction

The minimum time which the director should spend in the laboratory must be specified, and it must be related to the analyses which the laboratory attempts. There is a place for a small laboratory which does a few simple tests and refers more difficult work to another laboratory. Such a laboratory need be under only intermittent supervision by a professionally qualified person (for example, about four hours per week) but should be run by an experienced, reliable technician. By restricting the scope of the laboratory, defining minimum technician qualifications, and establishing a minimum number of hours per week of professional supervision, satisfactory operation could be ensured.

The more ambitious laboratories obviously require more intense professional supervision by individuals qualified in the specific services. To direct a large laboratory of wide scope and to maintain effective quality control, at least fifteen hours per week must be spent in the laboratory.

Quality Control

An effective quality control procedure should be in operation. Advice and education will be necessary to achieve this requirement.

Procedures and Equipment

Only satisfactory procedures and equipment should be used, and advice should be given on the latest methods and on the weaknesses of existing methods.

Licensing of Kits, Reagents and Equipment

It has been suggested that it may be desirable to control the use of prepackaged reagents or kits which are frequently used in private clinical laboratories. It is impossible to generalize about kits, because they differ considerably in the types of analyses which they are designed for, and they probably differ in quality as well. No attempt was made in this report to assess the reliability of kits. This task is being undertaken to some extent by the National Defence Medical Centre in Ottawa.

A conscientious director will not use a kit without thoroughly testing it. This is an expensive and time-consuming procedure, and some busy, poorly directed laboratories may use kits indiscriminately. Any consequent errors are the responsibility of the director, not of the manufacturers of the kit.

The same applies to reagents in general, where it is possible to economize by purchasing lower quality products; and to equipment, where the manufacturer's claims may be optimistic. The competent director will treat all suppliers' claims with some scepticism and satisfy himself by experiment that they are justified.

Kits are used by private clinical laboratories in blood grouping, for example, where they have proved very reliable. In biochemical analyses, kits often provide a simplified procedure with some loss in accuracy. This is fully realized by the laboratory; and where the degree of inaccuracy is acceptable, the use of kits instead of the usual method of determination is quite proper. In many laboratories where there is a shortage of skilled personnel to prepare reagents, the use of kits or prepackaged reagents probably reduces the frequency of mistakes due to the use of wrong reagents.

The danger lies in kits or new pieces of equipment being used by unqualified people as a substitute for skill and experience. Only in an inadequately supervised laboratory will this happen. It is to be hoped that, following the introduction of licensing, any such laboratories will improve or cease operation; therefore, licensing of kits or equipment will prove unnecessary. We conclude that there is no need for legislation to control the sale of kits, reagents and equipment.

Appendix I

List of Laboratories[1]

The laboratories are grouped as follows:

1) Independent clinical laboratories doing the normal tests
2) Chains of laboratories
3) Specialized laboratories.

Ownership or directorship links between two or more laboratories in groups 1 or 3 are given below:

Director	*Laboratories*
Dr. R. M. Clark, F.R.C.P.	Cyto-Pathology Consultants Clinical Pathology
Dr. C. A. Moodie, M.D., F.R.C.P.	St. Catharines Medical Laboratory Welland Medical Laboratory
Dr. M. Moscarello, Ph.D., M.D.	Boniface Park Medical Centre Sculac Medical Laboratory Specialized Biochemistry
Dr. W. W. Pascoe, M.D.	Three Zifkin Laboratories
Dr. W. L. Richards, M.D., F.R.C.P.	Two Lakeshore Laboratories

[1]This list was made at the time of the study during the period June to December 1967, and may be outdated by the time of publication.

1) Independent Clinical Laboratories Doing Normal Tests

Name and Address	Visited	Questionnaire Answered	Sample Sent	Analysis Received
Barrie Medical Arts Lab., 121 Wellington Street W., Barrie, Ontario.		X	X	X
Bathurst Diagnostic Lab., 648 Bathurst Street, Toronto, Ontario.	X	X	X	X
Bloor-Spadina Labs., 417 Bloor Street West, Toronto 4, Ontario.	X	X		
Boniface Park Medical Centre, 3474 Kingston Road, Scarborough, Ontario.	X	X	X	X
Brampton Medical Lab., 31 Centre Street, Brampton, Ontario.	X	X	X	X
Brant Arts Laboratories, 672 Brant Street, Burlington, Ontario.				
Brantford Clinic, Brant Avenue, Brantford, Ontario.	X	X		
Brockville Medical Clinic Ltd., 224 King Street East, Brockville, Ontario.				
Dr. D. W. Burgess, 97 Bridge Street East, Campbellford, Ontario.		X		
Caledonia Clinical Lab., 600 Caledonia Road, Toronto, Ontario.				
Carruthers Clinic, 137 Wellington Street, Sarnia, Ontario.				

1) Independent Clinical Laboratories Doing Normal Tests

Name and Address	Visited	Questionnaire Answered	Sample Sent	Analysis Received
Clinical Investigation Laboratories, 187 St. Clair Avenue West, Toronto, Ontario.	X	X	X	X
Clinical Pathology, 300 King Street West, Oshawa, Ontario.		X		
College Laboratory, 559 College Street, Toronto, Ontario.	X	X	X	X
Comprehensive Medical Laboratories, 190 Cosburn Avenue, #603, Toronto 6, Ontario.	X	X	X	X
Dr. A. Dickson, 427 Willowdale Avenue, Willowdale, Ontario.	X	X		
Doctors' Professional Lab., 241 Brock Street, Kingston, Ontario.			X	
Doctors' Professional Labs., Dr. R. Hughes, 241 Brock Street, Suite B, Kingston, Ontario.			X	
Don Park Laboratories, 1 Medical Place, 20 Wynford Drive, Don Mills, Ontario.	X	X		
Etobicoke Medical Centre, 150 The East Mall, Islington, Ontario.		X		
Glazier Medical Centre, 136 Simcoe Street North, Oshawa, Ontario.	X	X	X	X

1) Independent Clinical Laboratories Doing Normal Tests

Name and Address	Visited	Questionnaire Answered	Sample Sent	Analysis Received
Haematology Services, 170 St. George Street, Suite 430, Toronto, Ontario.	X	X	X	X
Hamilton Clinical Lab. Services, 452 Main Street East, Hamilton, Ontario.	X	X	X	X
Hamilton Medical Lab. Ltd., Medical Arts Building, Suite 110, 5 Young Street, Hamilton, Ontario.	X	X	X	X
Kay Medical Labs., 688 Coxwell Avenue, Toronto, Ontario.		X	X	X
Kipling Acres Home for the Aged, 1575 Kipling Avenue North, Rexdale, Ontario.		X		
Kipling Medical Laboratories, 1495 Kipling Avenue North, Rexdale, Ontario.				
Kitchener Clinical Lab., 751 King Street West, Kitchener, Ontario.	X	X	X	X
Lake-of-the-Woods Clinic, 112 Matheson Street S., Kenora, Ontario.		X	X	X
Lakeshore Laboratories Ltd., 207 Lakeshore E., Port Credit, Ontario.	X	X	X	X
Lakeshore Laboratories Ltd., 21 Upper Middle Road, Cooksville, Ontario.	X	X	X	X

1) Independent Clinical Laboratories Doing Normal Tests

Name and Address	Visited	Question-naire Answered	Sample Sent	Analysis Received
Lockwood Clinic, 300-312 Bloor Street East, Toronto 5, Ontario.	X	X		
London Medical Lab., 450 Central Avenue, Suite 203, London, Ontario.	X	X	X	X
Drs. MacKay and G. Elboon, 3000 Lawrence Avenue East, Scarborough, Ontario.				
McGregor Clinic, 250 Main Street East, Hamilton, Ontario.		X	X	
Malton Medical Group Lab., Malton, Ontario.		X	X	X
Medical Arts Lab., 1793 Main Street, Niagara Falls, Ontario.	X	X	X	X
Medical Arts Lab., Cumberland Street, Port Arthur, Ontario.				
Medical Centre, 106 Talbot Street W., Leamington, Ontario.			X	X
Medical Diagnostic Lab., 316 St. Clair Avenue West, Toronto 10, Ontario.	X	X	X	X
Medical Labs. of Windsor, 1466 Ouellette Ave., Windsor, Ontario.	X	X	X	X
Medical Testing Lab., 350 Beech Avenue, Toronto, Ontario.	X	X		

1) Independent Clinical Laboratories Doing Normal Tests

Name and Address	Visited	Question-naire Answered	Sample Sent	Analysis Received
Muskoka Lakes Clinic, Port Carling, Ontario.				
Dr. D. M. Noble, 152 Harwood Avenue S., Ajax, Ontario.	X	X	X	X
Northwestern Medical Labs., 911 Arthur Street, Fort William, Ontario.		X	X	X
North York Medical Lab., 33 Talbot Road, Willowdale, Ontario.			X	
Oshawa Clinic, 117 King Street East, Oshawa, Ontario.		X	X	X
Peterborough Clinic, 327 Charlotte Street, Peterborough, Ontario.				
Porphyria Labs., 253 Ontario Street, Kingston, Ontario.		X		
Port Arthur Clinic, 194 North Court Street, Port Arthur, Ontario.				
Quality Medical Laboratories Services Ltd., 158 St. George Street, Toronto 5, Ontario.	X	X	X	X
Queen Medical Centre, 1192 Queen Street East, Toronto, Ontario.		X	X	X
Dr. Peter Rado Laboratory, 1482 Bathurst Street, #207, Toronto 10, Ontario.	X	X	X	X

1) Independent Clinical Laboratories Doing Normal Tests

Name and Address	Visited	Questionnaire Answered	Sample Sent	Analysis Received
Sault Ste. Marie Group Health Centre, 240 McNabb Street, Sault Ste. Marie, Ontario.		X		
Sculac Medical Laboratory Ltd., 611A Bloor Street West, Toronto 4, Ontario.	X	X	X	X
Smith Clinic, 144 Main Street, Hawkesbury, Ontario.				
Specialized Biochemistry and Medical Laboratories, 394 Bloor Street West, #9, Toronto 4, Ontario.	X	X	X	X
Standard Biological Lab., 658 St. Richards, Cooksville, Ontario.				
St. Catharines Medical Centre, 292 Oakdale Avenue, St. Catharines, Ontario.		X	X	X
St. Catharines Medical Lab., Dr. Moodie, 157 Ontario St. & 163 Queenston St., St. Catharines, Ontario.	X	X	X	X
St. Clair-Dufferin Medical Centre, 2045 Dufferin Street, Toronto, Ontario.		X		
St. George Laboratories, 170 St. George Street, #635, Toronto 5, Ontario.	X	X		
Dr. Michael Stuparyk, 297 Old Kingston Road, West Hill, Ontario.	X	X	X	X

1) Independent Clinical Laboratories Doing Normal Tests

Name and Address	Visited	Question-naire Answered	Sample Sent	Analysis Received
Sudbury Bio-Assay Labs. Ltd., Dobson Building, 174 Larch Street, Sudbury, Ontario.			X	X
Sudbury Clinic, 130 Elm Street East, Sudbury, Ontario.				
Warren Lab. Services, Dr. S. L. Warren, 99 Avenue Road, Toronto 5, Ontario.				
Welland Medical Lab., Dr. Moodie, 80 King Street, Welland, Ontario.	X	X	X	
Winter Laboratories, 301 Lansdowne Avenue, Toronto, Ontario.	X	X	X	X
Yarmey Clinic, Dr. B. Eisen, 314 Bathurst Street, Toronto 2B, Ontario.				
Zifkin Biological Laboratory Ltd., 99 Avenue Road, Toronto, Ontario.	X	X	X	X
Zifkin Biological Laboratory Ltd., 3431 Bathurst Street, Toronto, Ontario.	X	X		
Zifkin Biological Laboratory Ltd., 459 Bloor Street West, Toronto, Ontario.	X	X		

2) Chains of Laboratories

Name and Address	Chain	Visited	Questionnaire Answered	Sent Sample	Analysis Received
Kopp Clinical Labs.					
Kopp Clinical Lab., 123 Edward Street, #310, Toronto 2, Ontario.	Kopp	X	X	X	X
Kopp Clinical Labs., Kemptville District Hospital, Kemptville, Ontario.	Kopp	X	X	X	X
Kopp Clinical Lab., 276 O'Connor Street, Ottawa 4, Ontario.	Kopp	X	X	X	X
Kopp Clinical Labs., Arnprior District Hospital, Arnprior, Ontario.	Kopp	X	X	X	
Kopp Clinical Labs., Almonte General Hospital, Almonte, Ontario.	Kopp	X	X	X	
Kopp Carleton Clinical Labs., Carleton Place Memorial Hospital, Carleton Place, Ontario.	Kopp	X	X	X	
Kopp Clinical Labs., Great War Memorial Hospital, Perth, Ontario.	Kopp	X	X	X	
Doctors' Clinical Laboratory Ltd.					
Doctors' Clinical Laboratory, 1849 Yonge Street, Toronto, Ontario.	DCL	X	X	X	X
Doctors' Clinical Laboratory, 221 Brant Avenue, Brantford, Ontario.	DCL		X	X	X
Doctors' Clinical Laboratory, 440 Hinton Avenue, Ottawa, Ontario.	DCL	X	X	X	X

2) Chains of Laboratories

Name and Address	Chain	Visited	Questionnaire Answered	Sample Sent	Analysis Received
Doctors' Clinical Laboratory, 283 Metcalf Street, Ottawa, Ontario.	DCL	X	X	X	
Doctors' Clinical Laboratory, 2286 Carling Avenue, Ottawa, Ontario.	DCL	X	X		
Toronto Medical Laboratory Ltd.					
Western Medical Laboratory, Suite 002-005, 25 Leonard Avenue E., Toronto 2B, Ontario.	TML	X	X	X	X
Oakville Medical Laboratory, 129 Reynolds, Oakville, Ontario.	TML	X	X	X	X
North Toronto Medical Laboratory, 250 Lawrence Avenue W., #203, Toronto, Ontario.	TML	X	X	X	X
Kingsway Medical Laboratory, 2917 Bloor Street West, Toronto, Ontario.	TML	X	X	X	
Keele-Ingram Medical Labs., 2221 Keele Street, Toronto, Ontario.	TML	X	X	X	
Pathologists' Services					
Concord Medical Labs., 895 Bloor Street West, Toronto, Ontario.	P-S	X	X	X	X
Parkdale Medical Clinic, 1271 Dundas Street West, Toronto 3, Ontario.	P-S	X	X	X	X

2) Chains of Laboratories

Name and Address	Chain	Visited	Questionnaire Answered	Sample Sent	Analysis Received
Raxlen Clinic (B), 25 Brunswick Avenue, Toronto 4, Ontario.	P-S	X	X		
Professional Medical Lab., 25 Brunswick Avenue, Toronto 4, Ontario.	P-S	X	X	X	X
North York Diagnostic Lab., 4949 Bathurst Street, Willowdale, Ontario.	P-S	X	X	X	X
Hillside Medical Laboratory, 2901 Lawrence Avenue E., Scarborough, Ontario.	P-S		X	X	X
Eglinton Medical Labs., 2600 Eglinton Ave. W., #103, Toronto, Ontario.	P-S	X	X		
Raxlen Clinic (A), 500 Parliament St., Toronto, Ontario.	P-S	X	X	X	X
Woodview Park Medical Centre, 3236 Weston Road, Toronto, Ontario.	P-S		X		
Willowdale Clinic, 30 Sheppard Avenue East, Willowdale, Ontario.	P-S	X	X	X	X
Keele Medical Centre, 3042 Keele Street, Toronto, Ontario.	P-S	X	X		
Queensway Medical Centre, 880 The Queensway, Toronto 18, Ontario.	P-S		X	X	X
Bloor Medical Centre, 609 Bloor Street West, Toronto, Ontario.	P-S	X	X	X	X

2) Chains of Laboratories

Name and Address	Chain	Visited	Questionnaire Answered	Sample Sent	Analysis Received
Albany Medical Centre, 200 Danforth Avenue, Toronto, Ontario.	P-S	X	X		
Ellesmere, 130 Ellesmere, Scarborough, Ontario.	P-S	X	X	X	
St. Barbara's Clinic, 226 Bathurst Street, Toronto, Ontario.	P-S	X	X	X	

3) Specialized Laboratories

Brampton Cytology Service, 4 Alderway Avenue, Brampton, Ontario.	(Cytology)
Cyto-Pathology Associates, 123 Edward Street, Toronto, Ontario.	(Cytology)
Cyto-Pathology Consultants, 300 King Street West, Oshawa, Ontario.	(Cytology)
Radioactive Isotope Laboratory, 123 Edward Street, Suite 1204, Toronto 2, Ontario.	(Radio-Isotope)
Allergy Laboratory Ltd., 25 Leonard Avenue, Toronto 2B, Ontario.	(Allergy Tests)
Renal Laboratories Ltd., 99 Avenue Road, Toronto, Ontario.	(Kidney Tests)
Le Ray-Strader Laboratory, 4823 Yonge Street, Willowdale, Ontario.	(Pregnancy Tests Only)

Appendix II

Results of the Quality Survey

Sample Preparation and Deduction of the "Assumed" Values

Five lots of liquid serum were prepared. These are designated A, B, C, D, and E. Two lots of freeze dried serum were used for SGOT analysis. These are denoted F and G. The lots were prepared as follows:

Lot A	equal vol. Versatol	(lot #0022027)	and Versatol A	(0091027)
Lot B	" " "	(lot #0090037)	" "	(0275047)
Lot C	" " "	(lot # 168047)	" "	(0019017)
Lot D	2 vol. Versatol A	(lot #0275047)	and 1 vol. Versatol	(0090037)
Lot E	2 vol. Versatol	(lot #0090037)	and 1 vol. Versatol A	(0275047)
Lot F	Versatol E	(lot # 159037)		
Lot G	Versatol E	(lot #0087027)		

The samples were given numbers which enabled them to be identified. No two samples were given the same number.

Analyses were supplied by Warner-Chilcott for each lot, from which the analyses of the mixtures could be calculated. Further, samples were sent to three reference laboratories and analyses obtained from them. The analyses of the A to E lots are summarized in Table A1.

It is apparent that the Warner-Chilcott assay values are very close to the mean of the reference laboratory results for all samples but bilirubin. In this case the discrepancy is probably due to bilirubin decomposition through exposure to light. The assay values were used as the "assumed true" values in all cases except the bilirubin — in which case the average of the reference laboratory results was used — and the glucose — in which case special treatment is necessary due to method variation. The SGOT results are shown in Table A2. Again the Warner-Chilcott results were used as the "assumed true" values.

The glucose results present a problem in interpretation, in that there are two distinct types of analysis which give different results. The Folin-Wu method measures glucose and other reducing sugars and is thus about 25 mg higher than other methods, such as the Nelson-Somogyi, which are more specific. To allow for this difference the glucose results were divided according to method and treated

TABLE A1

Assumed Values for Sample Lot Analyses

Lot	Analysis By	Glucose	BUN	Calcium	Sodium	Protein	Phos-phorus	Bili-rubin
A	W-C Assay	145	21.1	8.9	300	5.8	6.1	2.9
	TGH	145	22.0	—	302	5.5	5.8	2.5
	TWH	147	19.0	8.8	292	5.6	6.1	3.0
	D of H	141	20.0	9.0	300	5.7	6.1	2.0
	Assumed Value	1. FW 145 NFW 145 2. FW 160 NFW 134	21.1	8.9	300	5.8	6.1	2.3
B	W-C Assay	143	21.1	8.6	298	5.7	6.0	2.9
	TGH	149	22.5	—	303	5.8	6.3	2.5
	TWH	143	19.0	8.3	297	5.6	6.4	2.4
	D of H	145	20.0	8.5	298	5.6	8.6	1.9
	Assumed Value	1. FW 143 NFW 143 2. FW 158 NFW 132	21.1	8.6	298	5.7	6.0	2.3
C	W-C Assay	147	21.2	8.6	303	5.8	6.0	2.9
	TGH	150	22.5	—	303	5.9	5.9	2.3
	TWH	147	19.0	8.4	294	5.8	6.1	1.9
	D of H	144	20.0	9.0	300	5.7	6.0	2.0
	Assumed Value	1. FW 147 NFW 147 2. FW 162 NFW 136	21.2	8.6	303	5.8	6.0	2.3
D	W-C Assay	162	24.0	8.0	296	5.2	6.7	3.7
	TGH	134	24.5	8.0	292	5.4	—	2.9
	Assumed Value	1. FW [1] NFW 2. FW [1] NFW	24.0	8.0	296	5.2	6.7	2.7
E	W-C Assay	124	18.1	9.1	309	6.1	5.3	2.1
	TGH	66	18.5	9.1	304	6.4	—	1.6
	Assumed Value	1. FW [1] NFW 2. FW [1] NFW	18.1	9.1	309	6.1	5.3	

NOTES:

"W-C Assay" stated assay by manufacturer (Warner-Chilcott).
"TGH" Toronto General Hospital, "TWH" Toronto Western Hospital.
"D of H" Dept. of Health Public Health Laboratory, Toronto.
"FW" Folin-Wu Method; "NFW" Non-Folin-Wu—that is, "true" glucose.
[1]Results not used owing to evidence of sample deterioration.

TABLE A2

SGOT Samples

Manufacturer's and Reference Laboratory Analyses

SAMPLE	Manufacturer's (Warner-Chilcott) Analyses	Toronto General Hospital	Toronto Western Hospital
F	345 (Karmen) 361 (Babson) 297 (Reitman-Frankel)	345	314
G	294 (Karmen) 366 (Babson) 314 (Reitman-Frankel)	375	286

separately. It was found that the average Folin-Wu result was 15 mg higher than the assumed value and the others were 11 mg lower — that is, a method difference of 26 mg. This is in reasonable agreement with quoted differences.

The low results for the "Non-Folin-Wu" analyses are possibly due to sample deterioration in some cases, although the reference laboratory results show no such deterioration. Many laboratories probably were slow in analyzing the sample and did not refrigerate it properly. It was decided to calculate the performance in two ways: first, by an optimistic estimate, giving the laboratories the benefit of the doubt and assuming "true" values for each method corresponding to the mean of the results; and second, by a pessimistic estimate, using the assay value results. The use of the first (optimistic) method has the effect of reducing the apparent error by about 25 per cent. This treatment was necessary only in the case of glucose, the other analyses averaging close to the assumed value and showing no marked method dependence.

TABLE A3

Quality Survey Results

(Expressed As Deviations From Assumed Values)

Test	No.	Results	Mean	Std. Deviation
GLUCOSE (Folin-Wu) Assumed Value (1)	11	+25 + 23 +11 +2 +15 −10 +5 +18 +33 +37 +3	+14.7	Sum of Squares = 4420 (SD)² = 402 SD = 20.0 C of V = NA
GLUCOSE (Other than Folin-Wu) Assumed Value (1)	17 16 Used	+6 −2 −11 +3 −29 −25 +1 −49 −22 −19 +4 −4 +9 −30 −7 +3 −73†	−10.8	S of S = 5954 (SD)² = 372 SD = 19.3 C of V = NA
ALL GLUCOSE Assumed Values (2)	28 27 Used	+10 +8 −4 −13 +0 −25 −10 +3 +18 +22 −12 +17 +9 +0 +14 −18 −14 +12 −38 −11 −8 +15 +7 +20 −19 +4 +14 −62†	+0.0	S of S = 6141 (SD)² = 219 SD = 14.8 C of V = 10.2
BUN (mg/100ml)	49	−1.2 −3.3 +0.2 +1.0 +4.6 +0.3 −0.3 +1.9 +1.4 +2.1 +0.9 −2.6 +1.3 −0.2 +0.4 +3.6 +0.0 −2.1 +0.1 −3.4 −2.0 −3.5 +2.5 −2.4 +0.7 −1.2 −2.6 −0.8 +0.9 +0.1 −2.3 −3.5 −0.4 −0.2 −0.2 −6.5 +4.9 −1.1 +8.0 +0.0 +0.0 −2.0 −0.2 −1.0 +0.0 −1.5 +0.0 −3.5 −4.5	−0.3	S of S = 310.54 (SD)² = 6.34 SD = 2.5 C of V = 11.9
CALCIUM (mg/100ml)	21	+0.7 +0.4 +0.1 +0.1 +1.1 +0.6 +0.0 −0.3 −0.1 +0.9 +0.0 +0.5 −0.1 +1.6 +1.3 +0.4 +0.1 +0.3 +1.2 +1.0 +0.2	+0.5	S of S = 10.40 (SD)² = 0.49 SD = 0.7 C of V = 8.0
SODIUM (mg/100ml)	9 8 Used	+21 −141† +8 −1 −1 +8 +4 −8 −8	+3	S of S = 715 (SD)² = 89.4 SD = 9.5 C of V = 3.2
TOTAL PROTEIN (mg/100ml)	31	+0.6 +0.7 +0.0 −0.3 +0.1 +0.1 +0.4 +0.0 +0.0 +0.5 −0.6 +0.5 −0.1 +0.0 +0.3 +0.5 +0.1 −0.2 +0.3 −0.1 −0.2 −0.1 +0.3 +0.6 +0.1 +0.1 +0.3 +0.4 +0.5 +1.2 +0.5	+0.2	S of S = 5.19 (SD)² = 0.17 SD = 0.41 C of V = 7.0
PHOS-PHORUS (mg/100ml)	19	−0.2 −1.9 −1.4 −0.6 −0.6 +0.0 −0.1 +0.4 +0.1 −0.6 +0.6 −0.1 −0.8 +0.7 +0.5 +0.1 −0.4 −0.6 +0.0	−0.3	S of S = 9.15 (SD)² = 0.48 SD = 0.69 C of V = 11.5
TOTAL BILIRUBIN (mg/100ml)	31	+0.1 +0.2 +0.4 +0.9 −0.2 +0.1 +0.0 −1.3 −0.7 +0.5 −0.3 −0.2 −1.0 −0.5 −0.2 −0.5 −1.2 −0.9 −0.3 +0.0 +0.6 +0.8 −1.5 +0.0 +0.0 +0.1 +0.1 −0.6 +0.0 +0.2 +0.5	−0.2	S of S = 11.43 (SD)² = 0.37 SD = 0.61 C of V = 26

†Result not used in calculating standard deviation.

Other Surveys

It is important to distinguish between surveys which measure the *between* laboratory variation and those which measure the *within* laboratory variation. Inevitably the results of a sample analyzed a number of times by one laboratory will be closer than the results of analyses done by a number of laboratories. Campbell and Owen[1] show that the reproducibility *between* laboratories is usually at least twice the *within* laboratory reproducibility. It is of some interest to compare this survey with results of within laboratory surveys such as that of Copeland.[2] The Toronto Hospital Surveys by Young and Porter[3] primarily give data on the within laboratory performance of twelve hospitals. However, it is possible to deduce some *between* laboratory information by combining the within and between laboratory variances. This is done by adding the within laboratory variance to the variance of the means of the twelve laboratories and from this total variance calculating the between laboratory standard deviation.

The Tonks survey[4] of 170 Canadian laboratories in 1960 is useful in giving an estimate of the standard of hospital laboratories (100 bed hospitals).

Other survey sources of interest are

1) National Comprehensive Laboratory Survey (Kit 1 Report Chemistry), Standards Committee, College of American Pathologists, Chicago.

2) Small Hospital Laboratory Survey Report (1966), College of American Pathologists Standards Committee.

3) F. B. Desmond, *New Zealand Medical Journal*, Vol. 63, No. 716, 1964.

4) Hendry PIA Proficiency Surveys in Clinical Chemistry (1963), Report of Scientific Meeting, College of Pathologists of Australia.

5) Hendry PIA Proficiency Surveys in Clinical Chemistry (1965). (Reported by D. G. Campbell and J. A. Owen, *Clinical Biochemistry,* Vol. 1, No. 3, 1967.)

6) New York State Department of Health Summary of Clinical Chemistry Survey Number One (1965).

7) National Defence Medical Centre survey of seven Canadian laboratories. L. Cloutier, Department of Clinical Biochemistry, National Defence Medical Centre, Ottawa.

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[1] *Clinical Biochemistry,* Vol. 1, No. 3, 1967.

[2] *American Journal of Clinical Pathology,* Vol. 44, No. 252, 1965.

[3] *American Journal of Medical Technology,* March 1964, p. 99; and Fifth International Congress of Clinical Chemistry, Detroit, 1963.

[4] D. B. Tonks, *op. cit.*